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PERFORMANCE CHARACTERISTICS OF AN ARTIFICIAL HEART

BY

© DAVID T. MORRIS B.Sc. (Alberta)

A THESIS
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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled "Performance Characteristics of an Artificial Heart" submitted by David T. Morris in partial fulfillment of the requirements for the degree of Master of Science.

ABSTRACT

The project is a systematic study of the design, construction, and in vitro performance of a pneumatically driven total replacement artificial heart and driving mechanism which interacts with the inlet (left and right atria) and outlet (aortic and pulmonary arteries) pressures and flow rate while maintaining good physiological pressures and cardiac output. The pump is designed to replace the resected natural heart planted orthotopically within the chest and to be connected to an external power source and control system.

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UNITS

In medicine, the generally accepted system of units is the metric system. Whenever possible measurements reported in this thesis are consistent with the metric system. In some instances departures from the system are made when commanded by instrument scale readings of other units, by material specifications, or when a measurement is made more comprehensible by a change of units. The following is a list of conversion factors for weights and measures used in this thesis.

1 P.S.I. = 51.7 mm.Hg.

1 mil. = 0.001 in. = 0.00254 cm.

1 gm.cm/sec. = 9.8 x 10^{-5} watt

1 liter = 0.22 gallon (Br.)

CHAPTER I

INTRODUCTION

1.1 The Origin of the Problem

The heart is the body's natural biological blood pump. Throughout history the heart has held great mythological and aesthetic importance for man, always commanding considerable attention and concern. It is perhaps the heart's almost instantaneous reaction to emotions that has led people to believe that abstract feelings such as love and hate are initiated by the heart. To the benefit of modern science and perhaps to the disappointment of some romantics, research in the past few centuries has discovered that the heart has only one function; to perfuse the vital organs and peripheries of the body with a rich supply of blood.

Unfortunately, like the other vital organs of the body, the heart is also vulnerable to disease. Weaknesses of the heart such as stenotic or incompetent valves and conduction failures may be rectified with replacement valves and pacemakers, but when the myocardium (heart muscle) no longer functions, the only cure would be a replacement heart. The substitute heart could be either biological or artificial. It is the artificial replacement that is of particular interest to engineers.

1.2 The Effect of Cardiac Allografts Upon Artificial Heart Research

To some people the necessity of the artificial heart and the justification of further research is pending upon the as yet undetermined success of the biological heart transplant. It would appear through

closer examination that this is not the case. There are two possibilities; the transplantation technique will prove to be either widely acceptable or not. If acceptable as is yet undetermined, the artificial heart could play the important role of sustaining the life of a prospective host while waiting for a donor heart of compatible tissue type. This temporary support would help to eliminate mismatching of tissue due to hurried donor selection and would protect other vital organs of the body that suffer so greatly during the failing days of the host's native heart. If transplantation proves unacceptable the usefulness of the artificial heart would be unquestionable as a device for long time survival of patients suffering from irreversible cardiac damage. It seems evident that the temporary device would not have to meet such stringent requirements as its long term counterpart. Whereas the temporary device could be powered and controlled from a bedside module, the long term device would have to be entirely independent of extracorporeal components. It may be argued that until an attempt is made at implanting the power and control devices, the problems encountered are not critical enough to justify research. Again, under closer examination, the success of past attempts at an artificial heart both with and without implantable power sources appears limited to recipient survival times measured in hours and at best only a few days. Both types of prosthesis are still faced with the same basic problem; that of adequately duplicating the pumping characteristics of the biological heart. The existence of this unsolved problem certainly justifies continued research of artificial hearts with extracorporeal power sources.

1.3 Critique of Previous Work

The first investigator to attempt to plant a mechanical heart inside the body was a Soviet investigator named V.P. Demikhov.[1]* In 1937 he performed three such experiments, implanting in animals a pumping contrivance that was driven by a rotating shaft powered from outside and inserted into the animal through a tube in the chest wall. Demikhov returned to his investigations with five more experiments in 1958 but as far as is known has not pursued the work further.

In the United States the possibility of making an artificial heart that could be planted in the chest was explicitly discussed at the 1957 Annual Meeting of the American Society for Artificial Internal Organs. By the end of that year an experiment at the Cleveland Clinic was performed in which an air-driven artificial heart was planted inside the chest of a dog whose own heart had been resected. With the mechanical pump driving the blood through the dog's circulatory system the animal lived for ninety minutes.[1] This was the beginning of many experiments which were conducted under the direction of W.J. Kolff whose interest in the field was generated in 1948 when he started work on a heart lung machine following his development of the first artificial kidney in 1941.[1] Since his first experiment Kolff has remained a leader and many other researchers in the artificial heart field have at some time been associated with him. The first artificial hearts to appear in the Cleveland Clinic were all electrically driven and included an electro-magnetic pump designed by S.H. Norton[1]

---

*Numbers in brackets denote references on page 70.

and a pendulum type designed by Kolff and Globe Industries.[2] Both employed ventrical sacs housing the blood which were periodically collapsed by a rosette of solenoids in the electro-magnetic type and by a swinging motor driven pendulum in the case of Kolff's design. Kolff also tried a roller type pump employing a peristaltic action, but it too suffered from the same inadequacies as other electrically driven hearts.[1] They were all disappointingly heavy, weak, inefficient, and generated too much heat.

By 1959 other researchers were beginning to have favorable results. D. Liotta of Cordoba, Argentina, had already developed pumps employing membranes, bellows and rollers, leading to survival times in dogs of 13 hours.[3]

In 1960 there was a change to incorporating an external power source for the hearts; compressed air. This type of drive introduced a new principle from which to work; that of the collapsible sac ventricle. This principle employs resilient rubber sacs encased in a semi-rigid housing. When air is injected between the sac and the housing the contents of the former are expelled: the flow is controlled by two one-way check valves. T. Akutsu pioneered this principle along with Kolff,[4] and by 1964 was achieving survival times of up to 27 hours in dogs, which ate, drank, and behaved normally in other respects.[5,6]

These longer survival times were introducing new problems; the animals failed to survive not due to a malfunction of the pumping mechanism but due to the formation of blood clots, which broke loose to form emboli which lodged in different parts of the body, blocking the circulation. This problem focused attention on flow patterns around valves and within the

ventricles, and on the development of materials that were less thrombogenic.

About this same time M.E. DeBakey and C.W. Hall at the Baylor University College of Medicine were developing extra and intra-ventricular assistors of the air-driven sac type.[7] The first implantation of an artificial ventricular assist device in a human being took place in July, 1963, under the direction of M.E. DeBakey.[8] This type of artificial heart research favoring heart assist and not total replacement continued concurrently.

The following two or three years saw many short lived designs. Kenneth Woodward of the United States Army's Harry Diamond Labs. developed a pump based on the fluid amplification technique resulting in survival times up to 50 hours.[1] W.H. Burns and H.B. Shumacker at the Indianna University School of Medicine developed a motor and fluid driven pump exhibiting apparently favorable results.[9,10] Once again these pumps were excessive in weight and size thus initiating implantation problems: the sac type pumps were then beginning to take precedence.

D. Liotta had by this time joined the team of Hall and DeBakey and they began developing a diaphragm type heart similar to the sac type which could be considered either an assist device or a total replacement heart.[8,11,12] They were also experimenting with linings to improve the blood-sac interface. They lined the inner parts of the pump with nylon or dacron velour which promoted a living surface of fibrin helping to eliminate thrombos formation.[13] A refined prototype of the pump was implanted in a 47 year old male by D. Cooley of Houston, Texas, in the Spring of 1969, sustaining his life for 64 hours at which time the patient

received a cardiac allograft.[14] This isolated case is an indication of the progress that has occurred in only twelve or thirteen years.

Dr. Kolff is now directing an artificial heart program at the University of Utah with encouraging success with the help of C.S. Kwan-Gett and others. They are continuing their efforts with sac type hearts and achieving notable success specializing in heart control mechanisms.[14] There is evidence that in countries other than United States such as Czechoslovakia and the U.S.S.R. researchers are investigating artificial heart possibilities.[14]

During the evolution of the pumping mechanisms there has been an accompanying development of driving and control mechanisms. They range from simple three way solenoids and rheostats[14] to analogue computerized systems built by N.A.S.A.[15] There has also been a corresponding improvement in valve prostheses which has aided the success of prosthetic hearts.

1.4 Present Work

In the light of the most currently available literature it appears that the sac type principle (Figure 1.1) demonstrates the greatest potential of any artificial method by which blood may be pumped by a device within the chest. This is so because the sac type blood pump most closely mimics the action of the natural heart. It provides a pulsatile flow of near natural rate, volume, and velocities, and may possess a geometry similar to that of the resected natural heart. The slow, gradual partial collapse of the flexible sac presents the blood with a driving force very similar to that of the natural heart. The

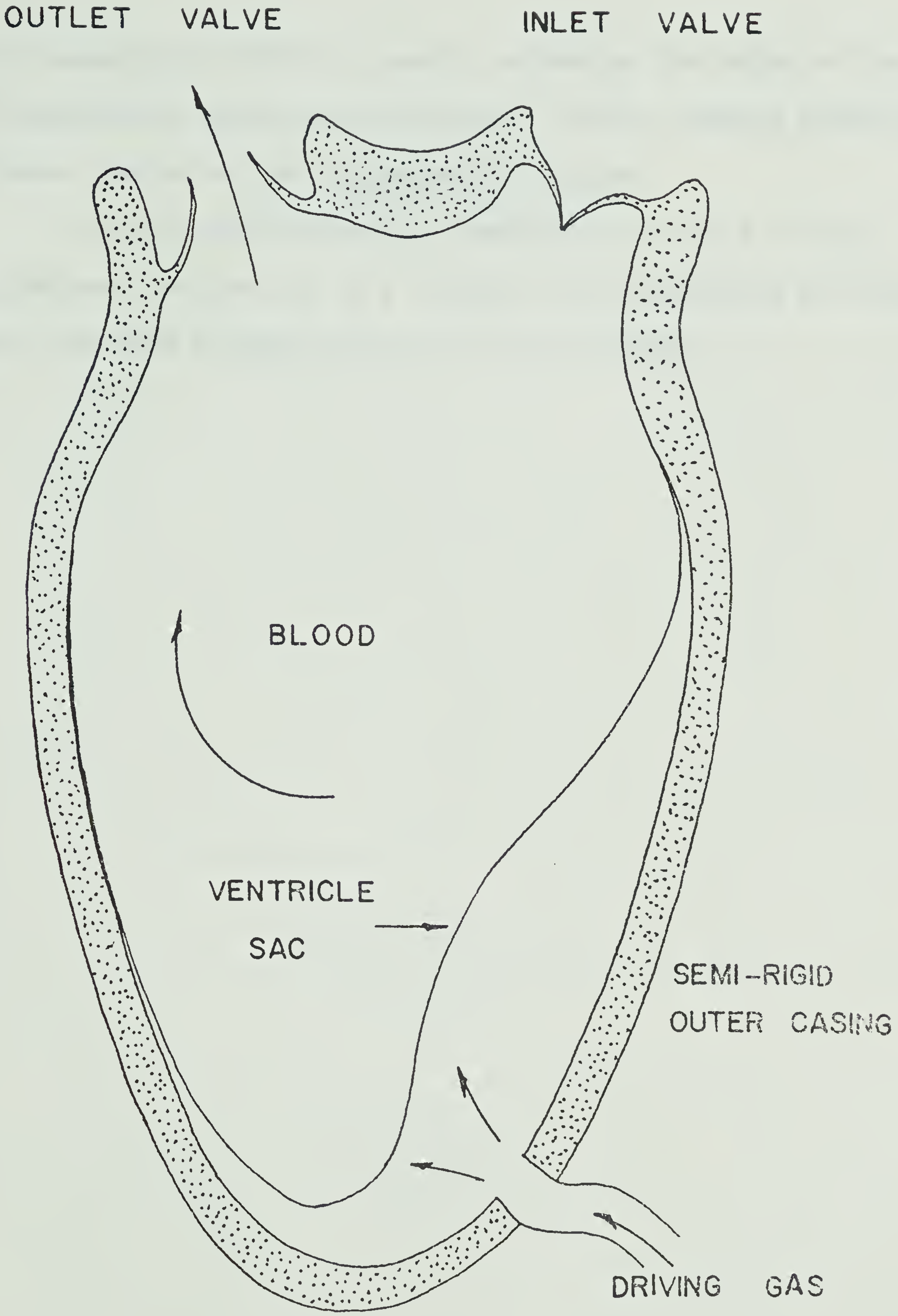

OUTLET VALVE
INLET VALVE
BLOOD
VENTRICLE SAC
SEMI-RIGID OUTER CASING
DRIVING GAS

FIG. 1.1 SCHEMATIC OF THE SAC TYPE ARTIFICIAL VENTRICLE — DURING SYSTOLE

principle possesses an intrinsic control mechanism; the output of the pump is governed by the degree of filling of the sac, greatly simplifying the external control and driving mechanism required.

It is for the above reasons, among others, that a sac type artificial heart (in addition to a suitable driving mechanism and testing apparatus) has been designed and built for this project.

CHAPTER II

THE CARDIOVASCULAR SYSTEM

2.1 Anatomy

The human cardiovascular system consists of two pumps connected in series with two circulations (Figure 2.1). The left ventricle pumps freshly oxygenated (red) blood through the aorta into the systemic circulation which leads to arteries going to the head, internal organs, and limbs. As the various organs are perfused with this oxygen-rich blood, oxygen is diffused from the blood into the cells of the organs. As the blood becomes depleted of its oxygen supply it changes to a blue color and returns to the right atrium and right ventricle by means of lesser and greater veins. The right ventricle pumps the blue blood through the pulmonary circulation (lungs) where oxygen from the atmosphere is diffused into the blood. The red blood produced then continues on to the left atrium and left ventricle by means of the pulmonary veins and the cycle thus continues.

The two ventricles work in unison, both discharging their load of blood simultaneously into their outlets or arteries. This phase of the heart; the expulsion of the blood by contraction of the ventricles, is called systole. The phase in which the ventricles are filled with blood, each from its own atrium, is called diastole. The left and right ventricles must pump an equal volume of blood over a period of time.

In the natural heart each atrium facilitates the filling of its

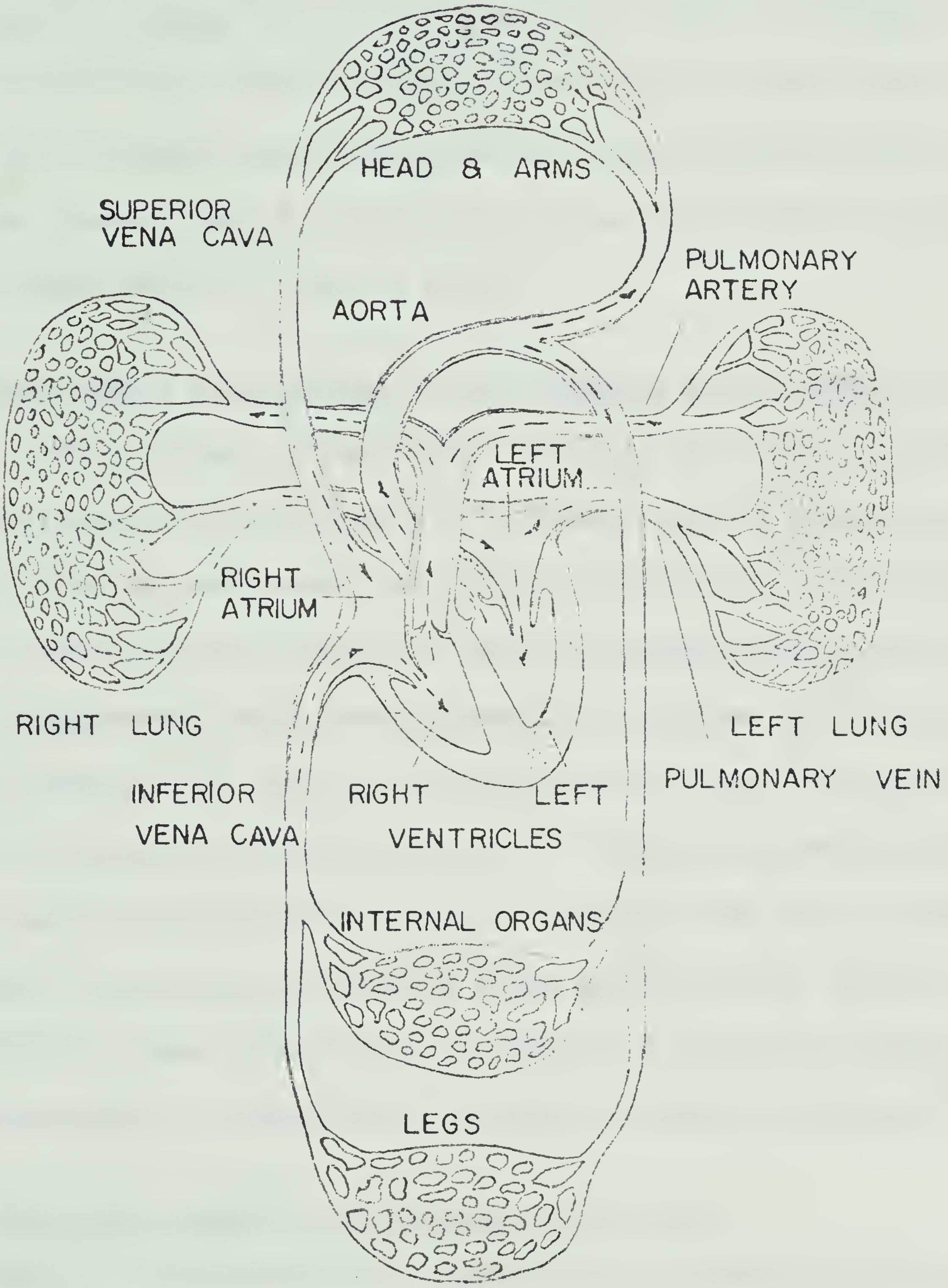

HEAD & ARMS
SUPERIOR VENA CAVA
PULMONARY ARTERY
AORTA
LEFT ATRIUM
RIGHT ATRIUM
RIGHT LUNG
LEFT LUNG
PULMONARY VEIN
INFERIOR VENA CAVA
RIGHT
LEFT
VENTRICLES
INTERNAL ORGANS
LEGS

FIG. 2.1 SCHEMATIC OF THE CARDIOVASCULAR SYSTEM

own ventricle by active contraction. This is, however, not absolutely necessary since the pressure in the filled atrium is sufficient to push blood into the relaxed half-filled ventricle. This is evidenced by people living normal lives without effective contraction of their atria owing to the lack of heart muscle co-ordination, known as atrial fibrillation.[1] The atria, however, must be completely collapsible so that as blood pours into the ventricles no vacuum is formed.

2.2 Physiological Requirements of the Pulmonary and Systemic Circulations

The pulmonary circulation is perfused with blood from the low pressure, right side of the heart. Pulmonary arterial pressure should be at least 20 mm.Hg. and capable of rising to 80 mm.Hg.[1] The systemic circulation is perfused with blood from the high pressure left side of the heart and aortic pressure should have a range of 120-180 mm.Hg.[1] The pressure in the pulmonary veins and superior and inferior vena cavae should be no more than 16 mm.Hg. nor less than zero.[1] Soon after implantation excessive suction may cause air sucking inside the pump and may cause a collapse of the venous system which could interfere with venous return. The perfusion volume should be no less than 1.5 liters per minute and should be capable of increasing to at least 5 liters per minute.[1]

2.3 Cardiac Requirements, Performance, and Control

Power Output - It is reasonable to expect that a patient with an artificial heart be satisfied with activity somewhat less vigorous than that expected from people with their own normal hearts. When computing heart power output it is assumed that kinetic energy is negligible compared with potential

energy of blood leaving the heart for low flow rates and that pulmonary pressure is one-fifth aortic pressure. These assumptions lead to an expression for the pressure work of the heart;[16]

$$\text{heart work} = \int P\,dv = 1.2\ (\text{mean aortic pressure})(\text{stroke volume}).$$

As can be seen in Figure 2.2 a range of power outputs has been calculated for people of different ages pursuing different activities. It can also be seen that for an average adult with two square meters body surface (Appendix A) a power output of 3 to 3.5 watts at a maximum flow rate of 9 to 10 liters per minute would allow for light to moderate work and a mean arterial pressure of 120 mm.Hg. As the flow rate mentioned would be a maximum, the patient would be able to perform more rigorous exercise but would receive the same indication of fatigue as would a normal person which would prevent him from undertaking prolonged excessive exercise.

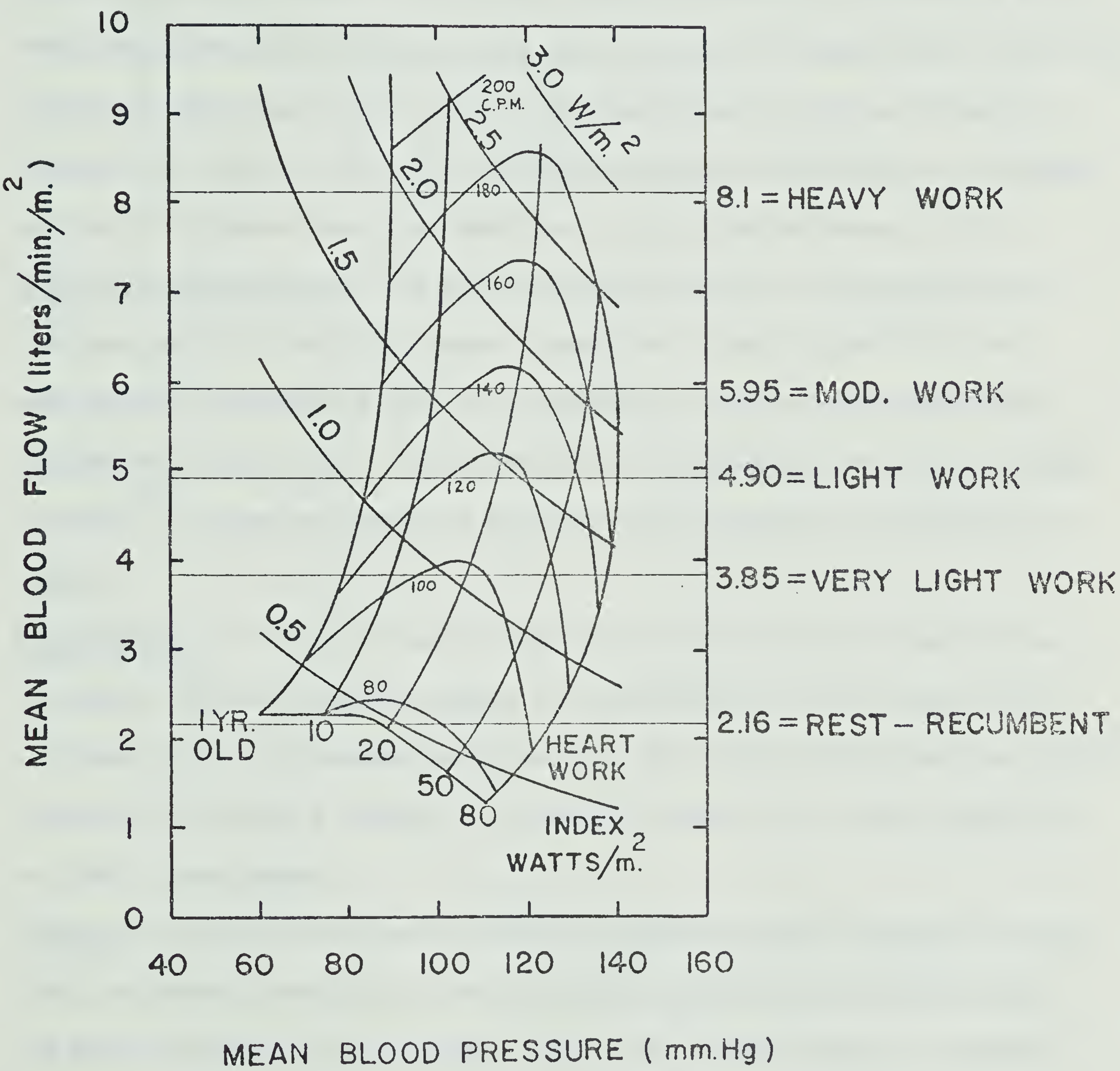
Physical Dimensions and Restraints - If the physiological heart were removed the vacated volume would be 3/4 to 1 liter.[16] The specific gravity of the pump should be close to unity which would minimize the necessary strength of restraints which should be able to withstand accelerations of 3 g. in order for the recipient to function in any position in our environment of 1 g.[17]

Ambient Pressure Changes - Changes of pressure due to weather and altitude changes may be as much as 20 mm.Hg. and intrathoracic pressures may reach 200 mm.Hg due to sneezes and voluntary Valsalva maneuver.[17] This is a factor requiring consideration particularly if the heart control is to be sensitive to inlet pressure.

CARDIAC INDEX FOR WORK LEVELS FROM

N.A.S.A. LIFE SCIENCE DATA BOOK (17)

(ASSUME 2 $m.^2$ AVERAGE BODY SURFACE)



PUMPING CHARACTERISTICS OF THE

FIG. 2.2 HUMAN HEART

Noise and Vibration - A minimum of noise and vibration would be desired to prevent the patient from being continually reminded of his ailment.

Service Life - If the replacement heart was to operate at the normal heart rate of 72 beats per minute[16] it would have to perform 3.8×10^7 pumping cycles per year. If the heart was not totally enclosed and free from connecting wires and tubes the cyclic action of respiration (8.0×10^6 cycles per year) would also have to be considered to have an effect on the service fatigue life. The ultimate prosthesis should have a designed service life longer than the remainder of the expected human life.

Waste Heat Dissipation - The physiological heart has the mechanism to dissipate up to 25 watts of power through the blood stream.[17] The body should therefore be able to accommodate losses of this order from a mechanical substitute. The critical blood temperature for blood damage is 43°C[17] rendering high heat and temperature producing components unusable.

Blood Damage - Artificial heart pumps are liable to be very destructive to blood. The most obvious damage is the hemolysis of red blood cells. The body is able to produce hemoglobin at the rate of 8.64 grams per day.[17] This would tolerate a pump with a hemolysis index of 0.1 grams hemoglobin per 100 liters pumped.

Surgery - An artificial heart should be capable of being inserted in the chest and being connected to the circulatory system with relative ease and should require no maintenance. While the natural heart is removed and the prosthetic device is being implanted the recipient's circulation can be maintained by a heart-lung machine effectively for several hours.

Control of Output - If the outputs of the two ventricles were not balanced, either the blood vessels in the lungs or those in the rest of the body would be filled to bursting with an excess accumulation of blood. In the natural heart, ventricle output is regulated by the principle known as Starling's Law.[18] The principle is that the output of each side of the heart is governed by the degree of filling of the ventricles, assuring identical flow rates. This type of intrinsic control of output balance is mandatory for an artificial heart. It is generally accepted that most, if not all control, is done outside the heart. The heart's ability to pump seems to be affected by many variables including the output pressure load, sympathetic and parasympathetic nervous regulation, heart rate, intrathoracic pressure, and myocardial damage. The amount of blood actually pumped is determined by the demand for blood throughout the body and is reflected as a change in atrial pressure. This function is illustrated in Figure 2.3 where the cardiac output of both left and right ventricles can be seen to increase with an increased atrial pressure (Starling's Law). The increased flow and increased atrial pressure occur together resulting in the feature that the heart responds to the atrial pressure with a high sensitivity. The normal right cardiac output curve has a slope of 4.3 litres per minute per mm.Hg. (Appendix E) at the operating point and the left cardiac output curve has a slope of 1.2 litres per minute per mm.Hg. at its operating point. The output of a ventricle is identified by the intersection point (equilibrium point) of the ventricle output curve with its respective venous return curve. The greater the demand for blood; the higher on the ventricle output curve is the equilibrium point.

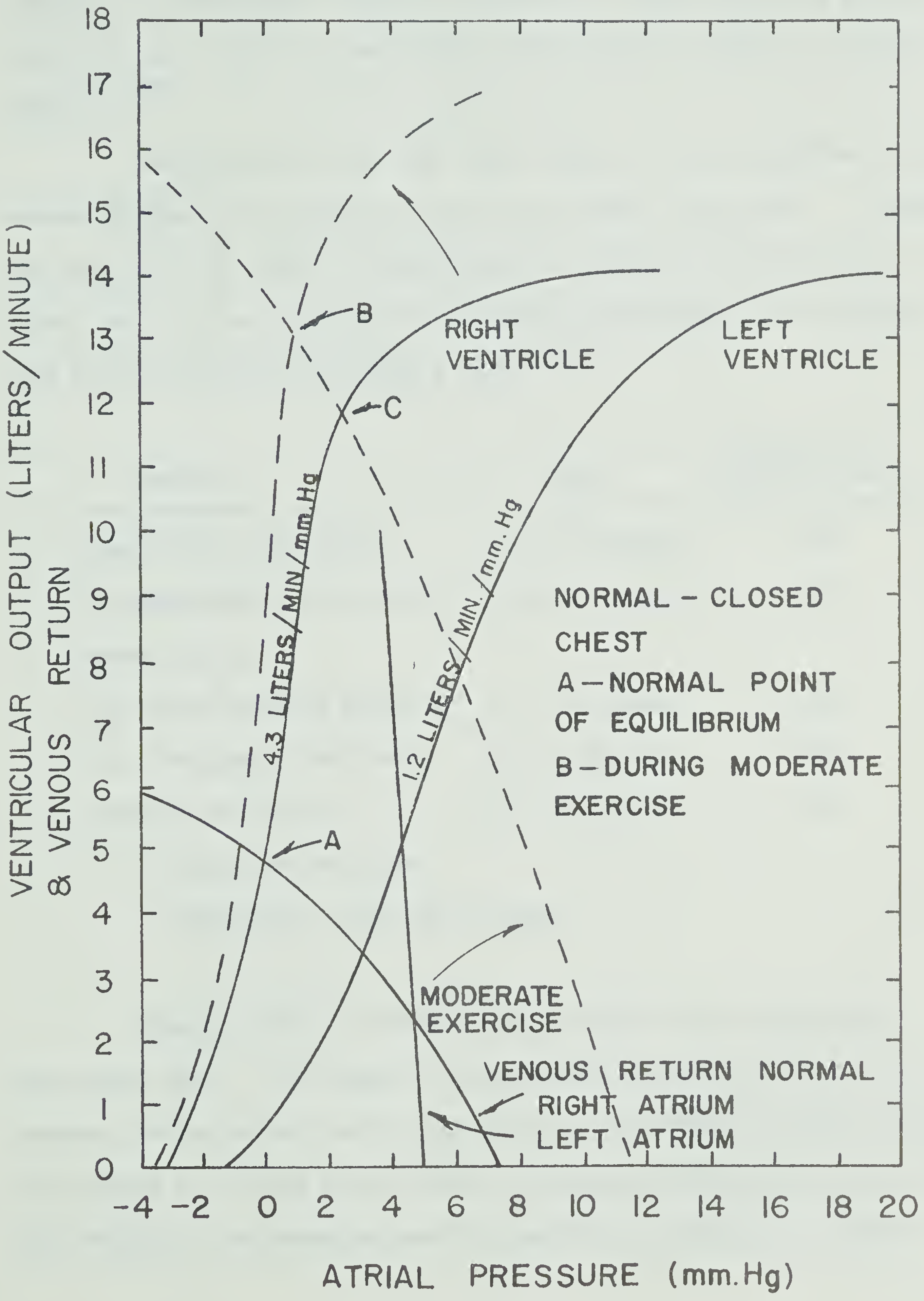


FIG. 2.3 STARLING'S REGULATION OF THE HEART (18)

Analysis of the response of the heart to output load has shown that atrial pressure is held almost constant regardless of load indicating that the ventricle has a very low sensitivity with respect to change in output pressure.[17]

The heart rate and thus heart output is also controlled by the nervous systems with mechanisms which are indeed complicated. In general the output of the heart is increased by an increase in heart rate. To assess the relative importance of regulatory mechanisms the following data were extracted from Guyton's book.[18]

Parameter	Range	% Change in Cardiac Output
+Sympathetic Stimulation	Zero to Maximum	20%
+Parasympathetic Stimulation	Zero to Maximum	10%
Venous Return		
*(a) Mean Systemic Pressure	4.7 - 15 mm.Hg	170%
*(b) Peripheral Resistance	$\frac{1}{2}$ - 2x Normal	100%
Arterial Resistance	$\frac{1}{2}$ - 3x Normal	20%

+ Venous Return Normal

* Sympathetic Stimulation Normal

Venous return is normally the dominant factor regulating the normal heart. For example, during moderate exercise 81% of the increased cardiac output can be attributed to the effect of venous return. From Figure 2.3 it can be seen that the change in right ventricular output resulting from moderate exercise (point A to point B) is caused

mostly by the increase in venous return (point A to point C) and only partially by the change in the ventricle output curve (point C to point B). It appears then that a prosthetic device controlled by venous pressure alone would satisfactorily accommodate the host with an adequate range of cardiac output.

From the above discussion it would appear that the primary function of the heart is to pump whatever volume of blood that appears at its inlet to the prevailing pressure level at its exit. The heart should not influence venous return nor should it be influenced by systemic arterial pressure. As a device, the heart may be described as having an extremely low hydraulic input impedance while filling, and a high output impedance while emptying.

CHAPTER III

DESIGN CONSIDERATIONS

3.1 The Pump

The heart design is that of a ventricle sac type driven by compressed air injected between a semi-rigid casing and the ventricle sac. It is four-chambered and contains four one-way check valves. The shape of the pump resembles that of the natural heart and consists of two independent sides to provide ease of atrial anastomosis. Each side has identical ventricles but different atria. The right side has a completely artificial jumbo atrium providing for direct cannulations to the inferior and superior vena cavae. The left side has a partial jumbo atrium which would require anastomosis to the left atrial remnant of the resected heart. These atria form large elastic reservoirs providing for rapid ventricular filling, eliminating the necessity of applying vacuum to the ventricles during diastole. This greatly simplifies the driving mechanism and obviates possible damaging effects to the venous system produced by negative pressure gradients. The pulmonary and aortic arterial connections are rubber necks providing for simple cannulations. The sacs, atria and arteries are designed to be made of natural rubber by dipping male wax molds into liquid latex. Commercially available heart values are incorporated and the ventricles are encased in a brushed on coating of clear polyurethane. The pumps are fitted with vents into all chambers for pressure monitoring, and tubes into the spaces between the ventricles

and casings to provide ports for the driving air (Figure 3.1 - 3.4).

The ventricles were considered first. Since both ventricles must pump equal volumes the first requirement is that they should be equal in size. The natural heart possesses ventricles of different shapes but apparently only to accommodate the unequal volumes of muscle in either side so that it would appear simplest to design both ventricles to have identical shape as well as equal volume. A very convenient shape is that of one-half of a semi-prolate ellipsoid such that when placed with their flat sides butting, the ventricles assume a form very similar to that of the natural ventricles involving no sharp corners or obvious clot-forming stagnation points. It is desirable, as is evidenced by the natural heart, to have a large residual volume in each ventricle to minimize blood forces and to provide a reserve for extra, short term output. A large residual volume is essential in the prosthetic heart to reduce high stresses in the ventricle sac and blood hemolysis owing to the rubbing of opposite sides of a highly evacuated sac. For a mean cardiac output of 5 litres per minute at 72 beats per minute the stroke volume of each ventricle would be 70 ml. Thus a ventricular volume of about 160 ml. provides for a considerable residual volume (55%) even under maximum output conditions where stroke volume would increase to 120 ml. (25%).

The atrial design had to include not only volume and compliance but, more critical, the orientation of their inlets to accommodate the vessels to which they would be anastomosed (Figure 3.5). The simplest atrium is one that is completely artificial and connectible to veins by

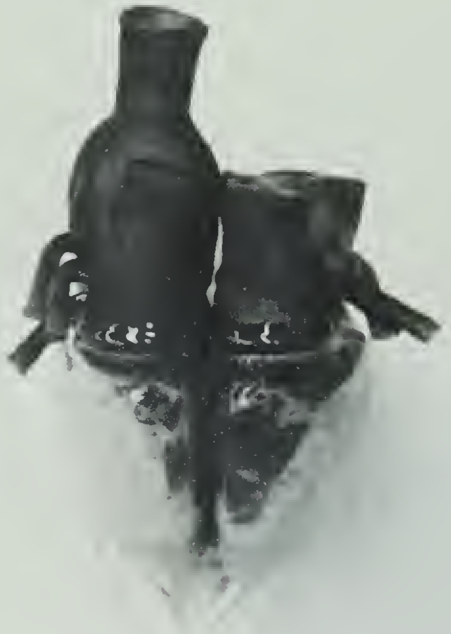


FIG. 3.1 PUMP - SIDE VIEW

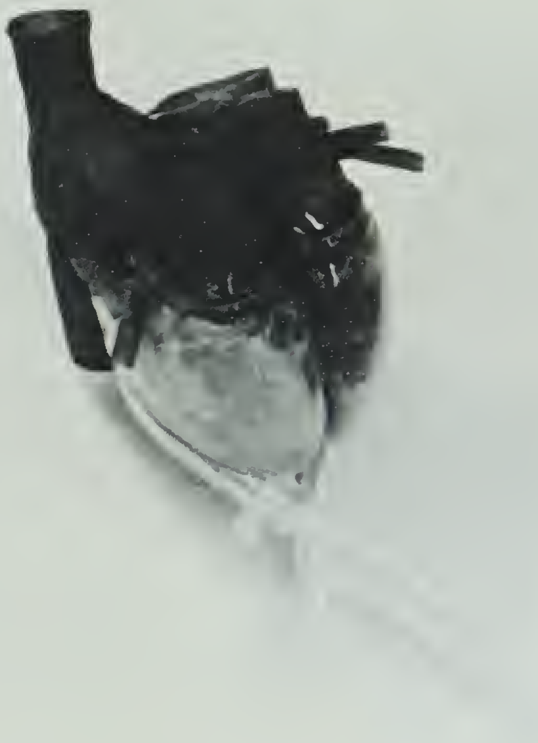


FIG. 3.2 PUMP - SIDE VIEW

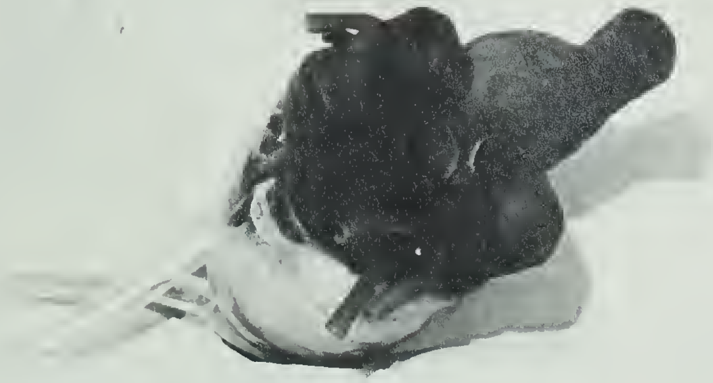


FIG. 3.3 PUMP – TOP VIEW

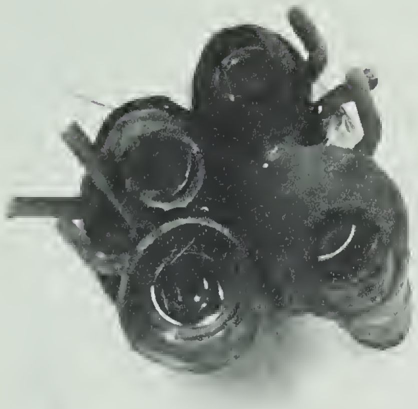


FIG. 3.4 PUMP – TOP VIEW

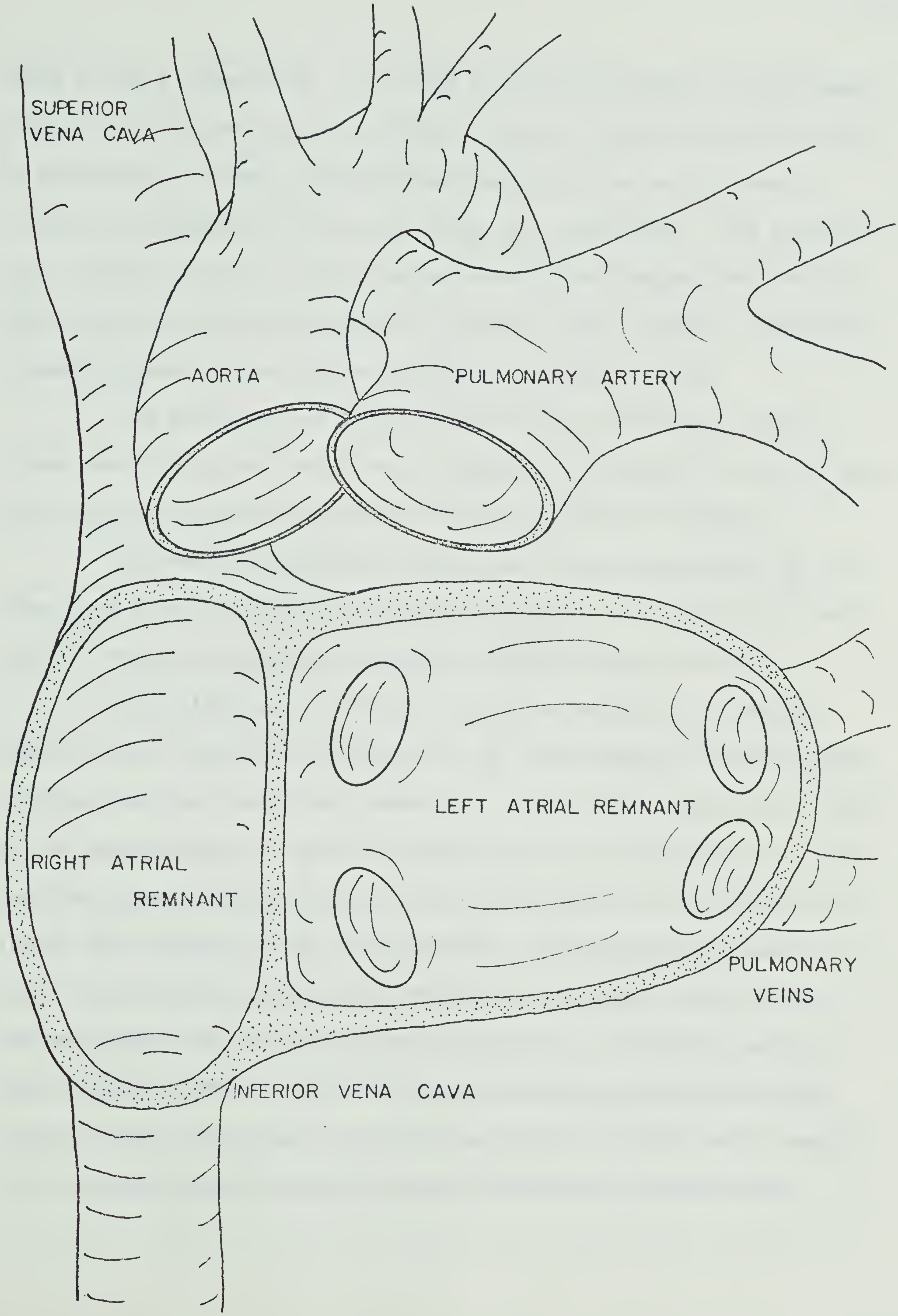

SUPERIOR VENA CAVA
AORTA
PULMONARY ARTERY
LEFT ATRIAL REMNANT
RIGHT ATRIAL REMNANT
PULMONARY VEINS
INFERIOR VENA CAVA

FIG. 3.5 REMNANTS OF CARDIAC RESECTION

means of quick cannulation. The right atrium was designed in this manner along with short vena cavae and had an internal volume of 115 millilitres. By examination of sheep, dog and human hearts in vivo and ex vivo, a suitable orientation of the venous stumps was established. The pulmonary veins are not so easily cannulated so a partial atrium was used for the left side which, when anastomosed to the left atrial remnant, should form a jumbo atrium of volume similar to that of the right atrium.

The pulmonary and aortic arteries were simulated by rubber stumps about 5 cm. long and 2 cm. in diameter and occupy 25 to 30 ml. each. They too were oriented to approximate with the arterial remnants.

Following construction, weight and volume measurements of the heart were made using direct and indirect methods. The results are tabulated in Figure 3.6 making a comparison with the natural heart.

Since the pump is similar in size and weight to the natural heart no extra restraints would have to be incorporated to hold the pump in situ other than the direct connections to the blood vessels left behind by the resected heart. The only significant force occurring would be the reactive force to the outflow of blood during systole, which should be no larger than produced by the natural heart. The implanted pump would appear less active than the natural heart due to its more rigid casings and consequent lack of contraction and dilatation. Since the casing is semi-rigid the effect of thoracic pressure upon output pressure should be very slight. There may be a slight variation in output due to varying atrial pressure resulting from varying intrathoracic pressure while

breathing, as is the case with a natural heart.

FIG. 3.6

Comparison of Weight and Volumes of
Artificial and Natural Hearts

	Natural Heart[16]		Artificial Heart	
	Left	Right	Left	Right
Ventricular Volume	115 ml.	115 ml.	160 ml.	160 ml.
Atrial Volume	85 ml.	85 ml.	50 ml.	115 ml.
Arterial Volume	-	-	25 ml.	25 ml.
	200 ml.	200 ml.	235 ml.	300 ml.
Total Blood Capacity	400 ml.		535 ml.	
Volume of Structural Material			93 ml.	108 ml.
	300 ml.		201 ml.	
Total Volume After Diastole	700 ml.		736 ml.	
Weight of Heart (Empty)	≈ 300 g.		94 g.	108 g.
			202 g.	
Specific Gravity of Heart	≈ 1		202/201 ≈ 1	

3.2 The Timing and Driving Unit

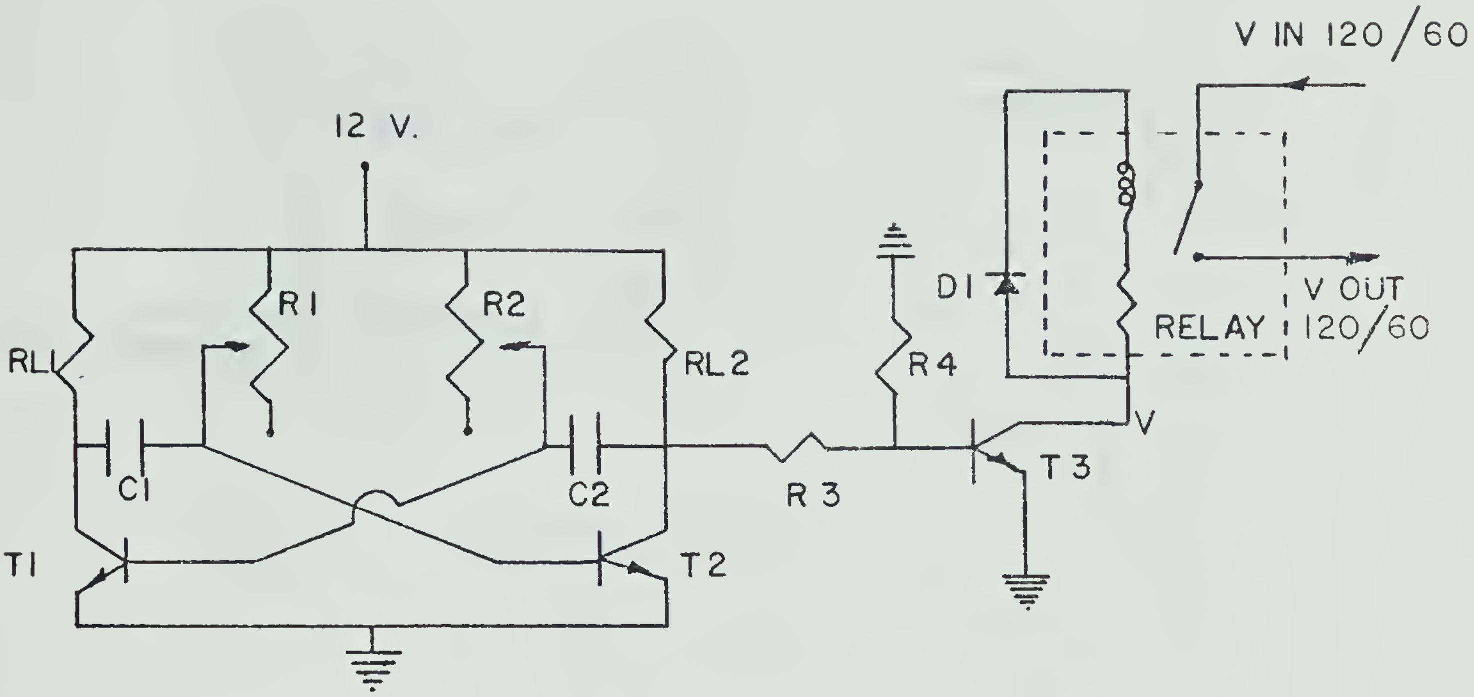
The timing and driving system must be capable of delivering compressed air of variable pressure to each side of the heart independently, with a variable systolic and diastolic duration. Working pressure may range from 0 to 10 psi and diastolic and systolic duration should range from 0 to 1 or more seconds to allow a minimum of 30 strokes per minute.

The system consists of pressure regulators, pressure gauges, three-way air pressure piloted solenoid valves, and a simple vibrator

electronic circuit (Figure 3.7) to control the pulses to the solenoid valves. The regulators are controllable from 0 to 40 psi. The diaphragm gauges register from 0 to 15 psi and the valves have 1/4 inch orifices which is important to allow for rapid exhaust of the evacuated ventricles during diastole. The system is designed to accept any source of air supply between 15 and 300 psi. Systole is variable from 0 to 1.5 seconds and diastole from 0 to 6 seconds. Figure 3.8 illustrates the design of the integral driving and timing unit fitted in a convenient stand (Figure 3.9 and 3.10).

3.3 The Mock Circulations

The mock circulations consist of multi-columnar plexiglass tanks capable of producing variable inlet (atrial) and outlet (diastolic) pressures, and to some extent a variable capacitance. The atrial pressure is adjusted by merely adding or removing fluid from the test chamber (Figure 3.11) allowing a variation from -8 to +24 mm.Hg. Diastolic pressure is adjusted by pumping air in or out of chambers 1, 2 or 3, which varies the differential in fluid level from one chamber to the next; the total pressure at (B) being the summation of all differentials. By employing many columns it is possible to produce a back pressure of several hundred mm.Hg. in a chamber only 50 cm. high. Flow rate is measured by an orifice meter calibrated to indicate litres per minute (Appendix B). The chambers for right and left sides differ only in the number of columns; the right side having four columns producing pressures from 20 to 90 mm.Hg. and the left side having nine columns producing pressures from 20 to 200 mm.Hg. Both chambers are designed to fit together allowing a cross over of outlet pipes from


V IN 120/60
12 V.
D1
R1
R2
RL1
RL2
R4
RELAY
V OUT 120/60
V
C1
C2
R 3
T 3
T1
T2

T1, T2, T3, — 2N163 TRANSISTORS

C1, C2, — 100 μfd. CAPACITORS 2 V. dc

R1, R2, — 100 KΩ, 25 KΩ POTENTIOMETERS

R3, R4, — 1/4 WATT RESISTORS 5KΩ, 50 KΩ

RL1, RL2, 1KΩ, 500 Ω

D1 — DIODE IN3122

RELAY 12 V. dc

DIASTOLE, $T1 \approx 0.7 (R1)(C1) \approx (0-7 \text{ SEC.})$

SYSTOLE, $T2 \approx 0.7 (R2)(C2) \approx (0-1.75 \text{ SEC.})$

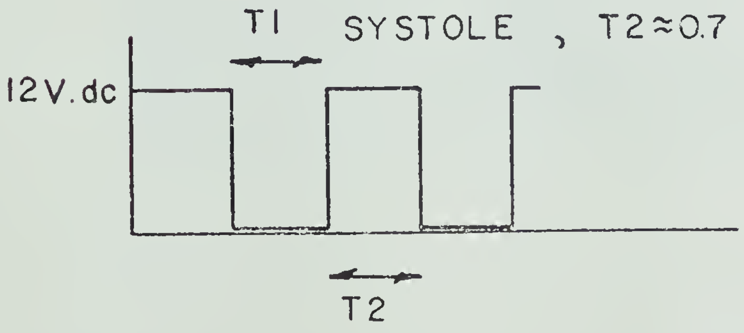


FIG. 3.7 SCHEMATIC OF TIMING CIRCUIT

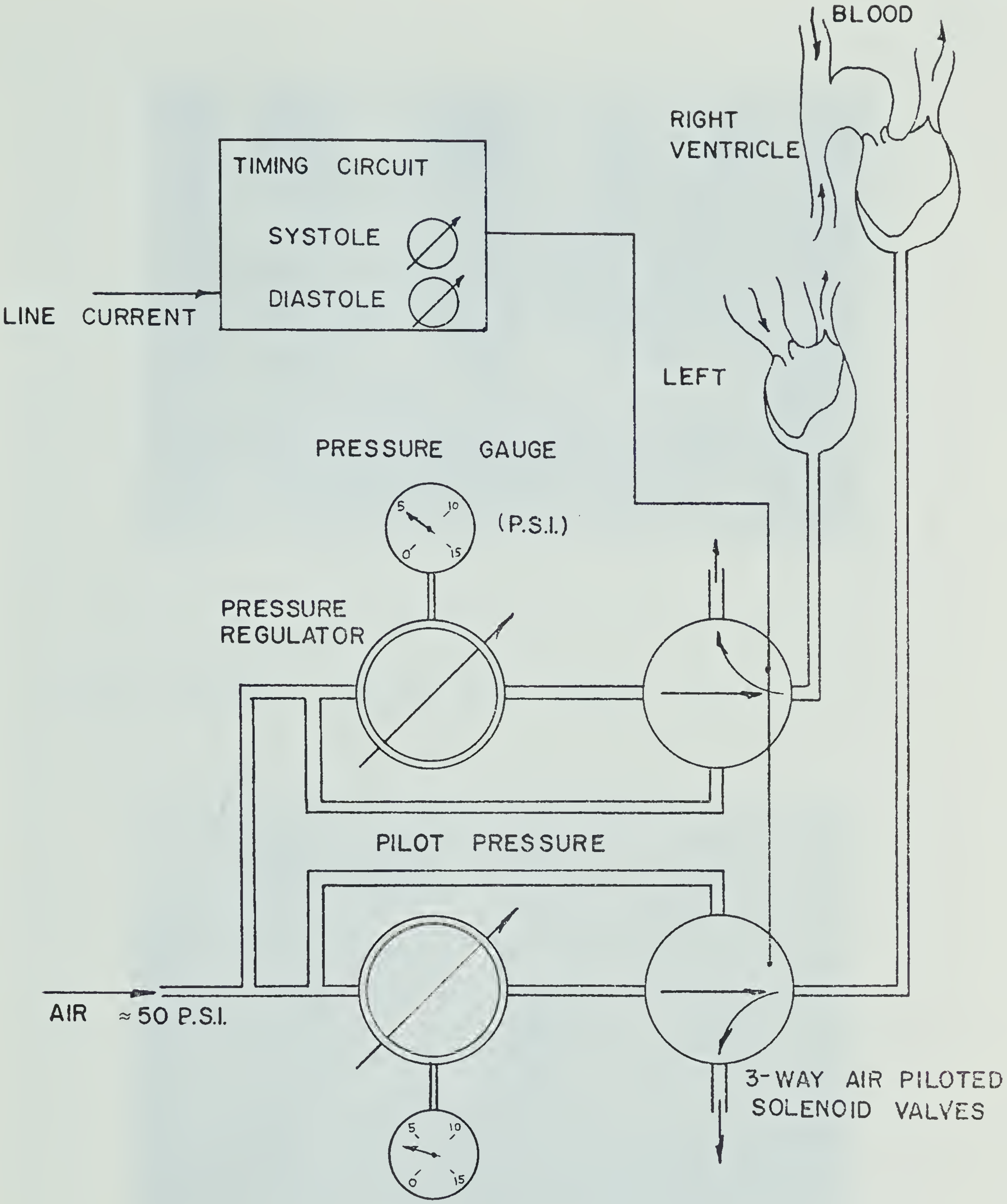

BLOOD
RIGHT VENTRICLE
TIMING CIRCUIT
SYSTOLE
DIASTOLE
LINE CURRENT
LEFT
PRESSURE GAUGE
5
10
0
15
(P.S.I.)
PRESSURE REGULATOR
PILOT PRESSURE
AIR ≈ 50 P.S.I.
5
10
0
15
3-WAY AIR PILOTED SOLENOID VALVES

FIG. 3.8 SCHEMATIC OF TIMING & DRIVING DEVICE

[illegible]

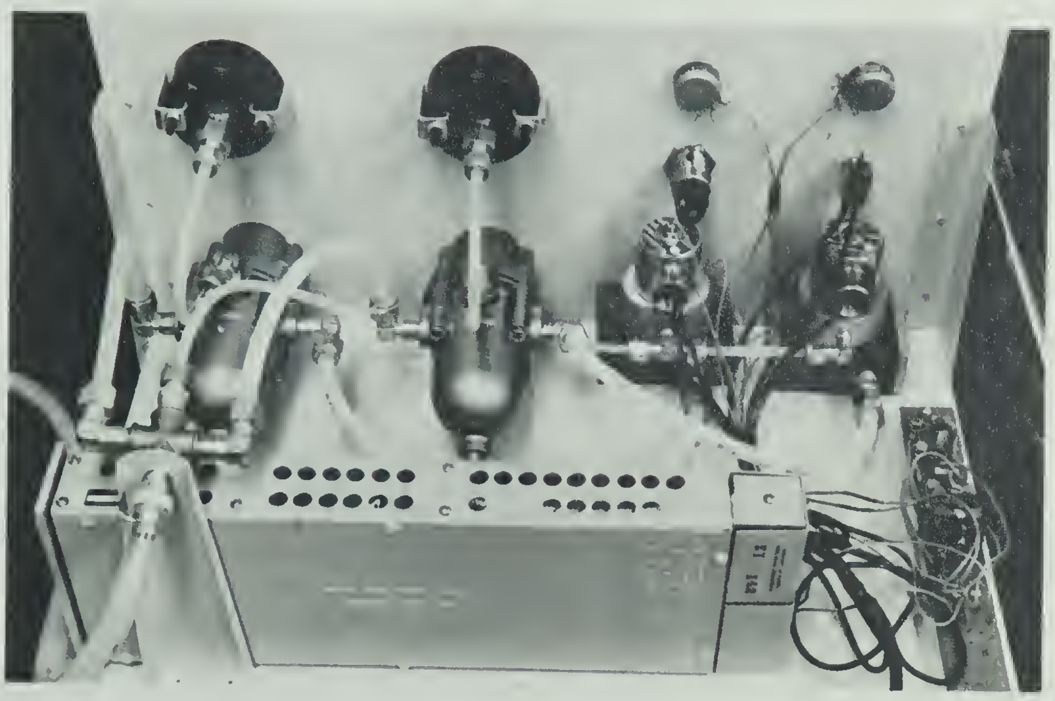


FIG. 3.9 TIMING & DRIVING UNIT — BACK VIEW

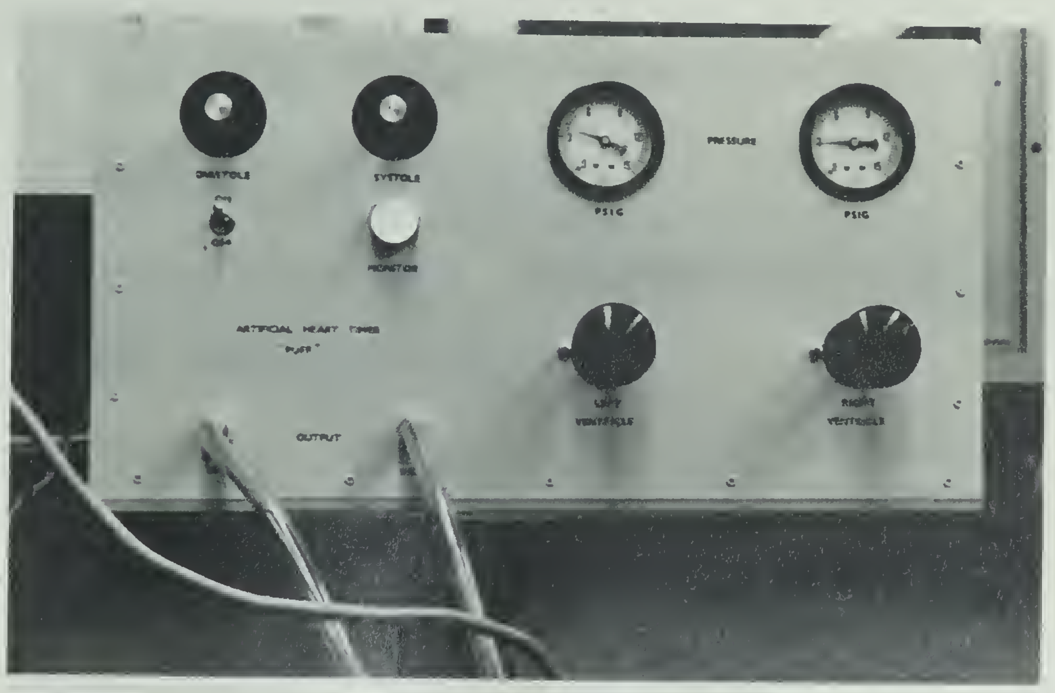
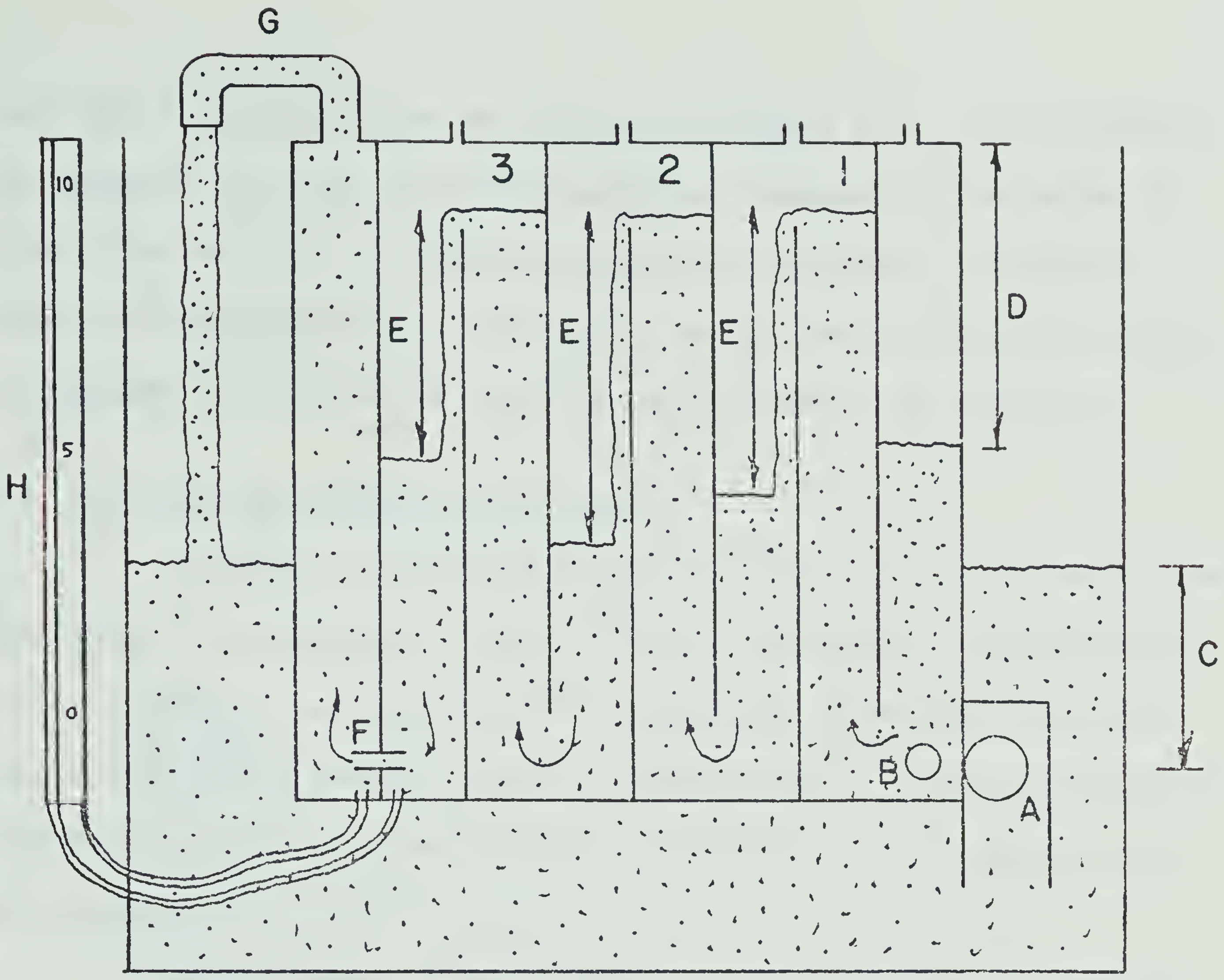

DIASTOLE
SYSTOLE
PRESSURE
PSIG
PSIG
MONITOR
ARTIFICIAL HEART TIMER
OUTPUT
LEFT VENTRICLE
RIGHT VENTRICLE

FIG. 3.10 TIMING & DRIVING UNIT — FRONT VIEW



A. INLET TO PUMP

B. OUTLET FROM PUMP

C. VARIABLE INLET PRESSURE BY ADDING OR REMOVING FLUID

D. VARIABLE CAPACITANCE BY VARYING HEIGHT OF AIR COLUMN

E. VARIABLE OUTPUT RESISTANCE BY VARYING HEIGHT OF AIR COLUMNS

F. ORIFICE METER INDICATING FLOW RATE

G. OUTLET PIPE

H. FLOW METER

FIG. 3.11 SCHEMATIC OF MOCK CIRCULATION

the right to the left side and vice versa (Figure 3.12). This connects the chambers in series with the right side representing the pulmonary circulation and the left side representing the systemic circulation. With an interconnected test device such as this the effects of a change in pressure or flow rate on one side can be examined on the other.

3.4 Materials and Manufacturing Details

In general, artificial heart materials which reside within the body should be biologically inert;[19] non carcinogenic, non antigenic, non electrolytic, and non toxic.[20] Materials in contact with blood should also be non hemolytic and clot repellant.[20] These requirements have been considered in the choosing of materials for the construction of the pump.

Natural rubber is one of the strongest elastic materials but has for a long time been believed to be unsuitable for implantation in the living body. It has since been discovered that specially treated pure natural rubber causes little tissue reaction and is compatible with blood.[19] Polyurethane, the other material used in the pump construction, is known to have excellent qualities for implantation causing no known degradation to the body. Some studies[21] have indicated that polyurethane looses strength after many months implantation but remains as a very useful plastic for short term applications.

The manufacture of a complete pump involves many stages which will be discussed in their chronological order. The core of the pump is the rubber sac which forms the ventricle bags, necks, atria and arteries for each side. The sacs are thin and are best made by dipping a male mold

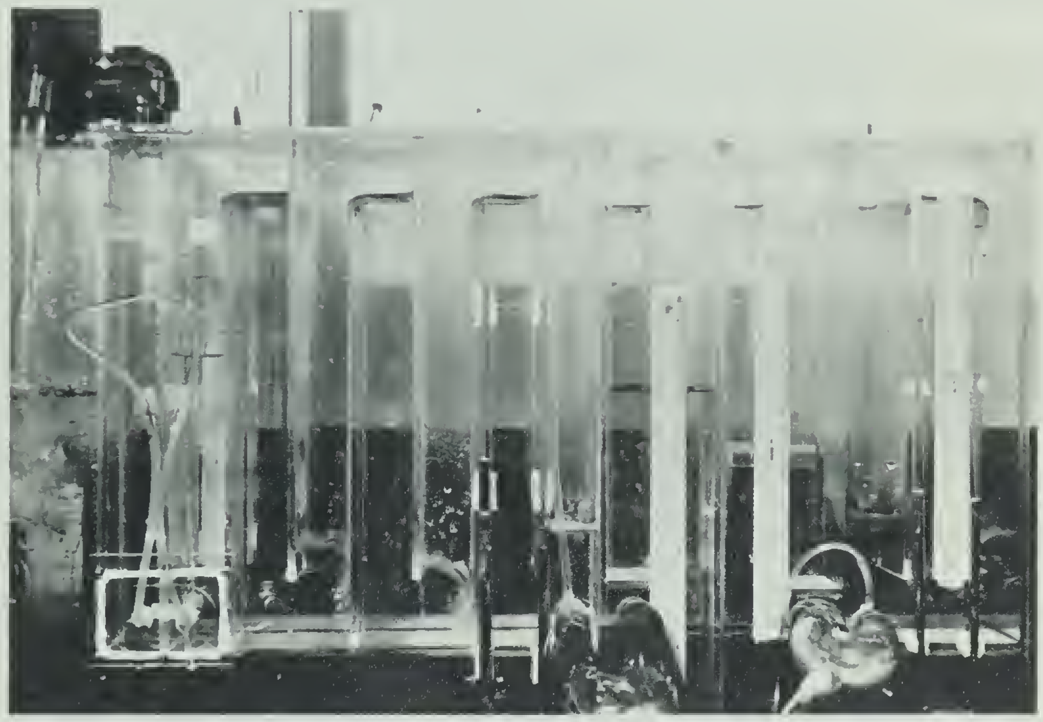


FIG. 3.12 MOCK CIRCULATIONS — CONNECTED IN SERIES

several times into a liquid latex. The prototype sac forms were hand carved from blocks of pink dental wax (Appendix C.1) and smoothed with a flame to approximate the desired shape. The impressions of these forms were made in room temperature vulcanizing rubber (Appendix C.2) which produced reusable female molds for casting of male paraffin wax (Appendix C.3) molds. These male forms were the same shape as the prototype but could be customized to accommodate various valve sizes by reducing the neck size. These paraffin forms were next dipped from 4 to 7 times (depending upon the rubber used)(Appendix C.4) into room temperature curing liquid latex. Each successive coating of latex vulcanized completely with the one before producing a smooth uniform sac of about 50 mills thickness. After several days curing the bags were each fitted with two one-way valves. The valves were fitted in the rubber necks between atria and ventricles and held in place by a simple wire clamp pressing part of the rubber into the circumferential notch found in all valves after removal of suture cuffs. Before applying the polyurethane outer casing the rubber ventricles were dipped in liquid parawax up to the necks to prevent sticking of the rubber to the polyurethane. The desired thickness (Appendix C.5) of polyurethane was achieved with about 8 to 10 brushed on coats taking about 5 days to apply with curing periods between coats. The air inlet/outlet port (Appendix C.6) was added at about the fourth coat. Following several days curing of the polyurethane the pump was completed. The fabrication sequence is illustrated in Figure 3.13.

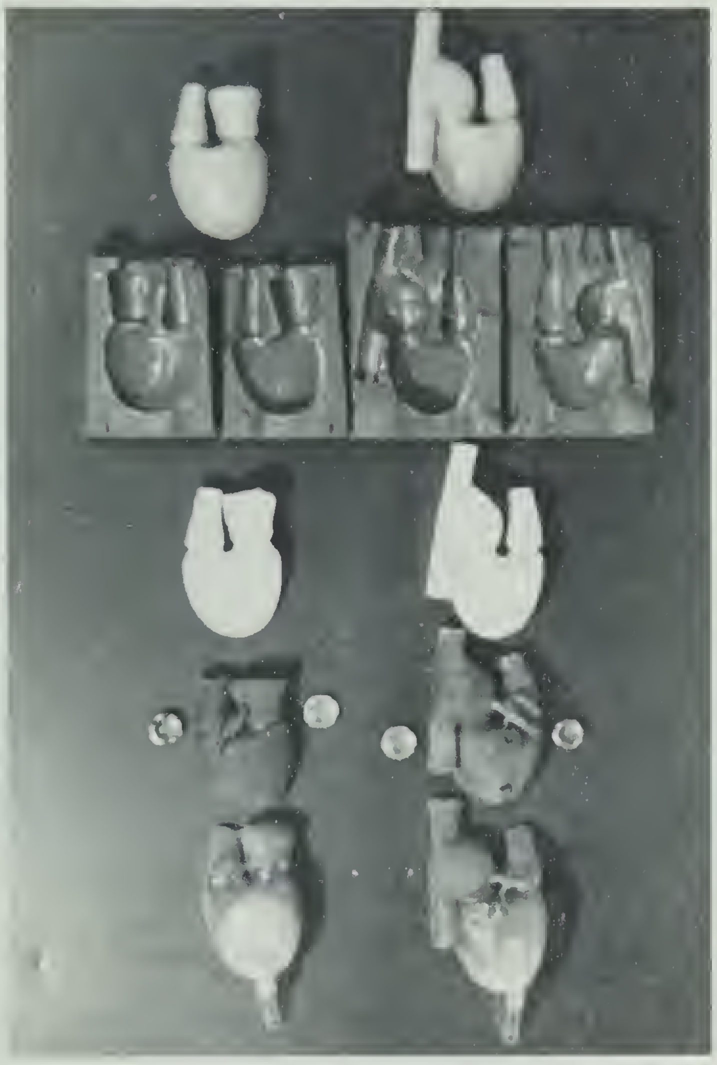


FIG. 3.13 PUMP FABRICATION SEQUENCE

CHAPTER IV

PERFORMANCE TESTS

4.1 Starling's Regulation - Fixed Rate

The first tests conducted established the duration of systole and diastole to produce optimum output and response to atrial pressure. All tests were conducted on the same pump which was fitted with Kay-Shiley disc valves.

The test equipment (Figure 4.1) consisted of the pumps, driving and timing unit, testing chambers, Sanborn Chart Recorder for measuring and recording all pressures, and oscilloscope to measure systolic and diastolic durations. For simplicity water was used as the pumping fluid. Blood has a viscosity of 3.5 to 5.4 times that of distilled water and a specific gravity of 1.048 to 1.06.[22] A suitable blood analogue consists of a 36.7% by volume glycerol solution.[23] A test was made with such a solution varying atrial pressure. Figure 4.2 reveals that the results using the glycerol solution compare very favourably with those using water, justifying the use of water.

4.1.1 Response to Varying Atrial Pressure

The left side was connected to the testing chamber, diastolic pressure was set at 90 mm.Hg, driving pressure at an arbitrary 5 psi, and atrial pressure at the maximum encountered in the body; 16 mm.Hg. Systole and diastole were selected by trial for maximum output which was 9 liters per minute at 0.28 seconds systole and 0.47 seconds diastole; the rate

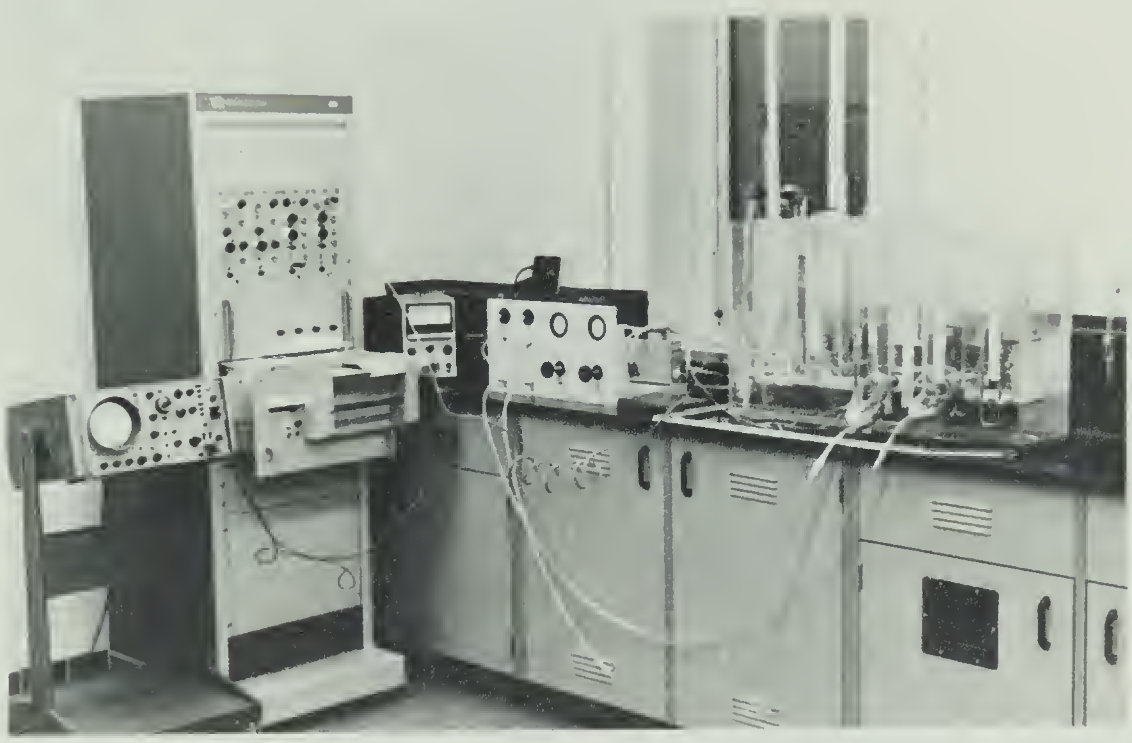


FIG. 4.1 TESTING APPARATUS

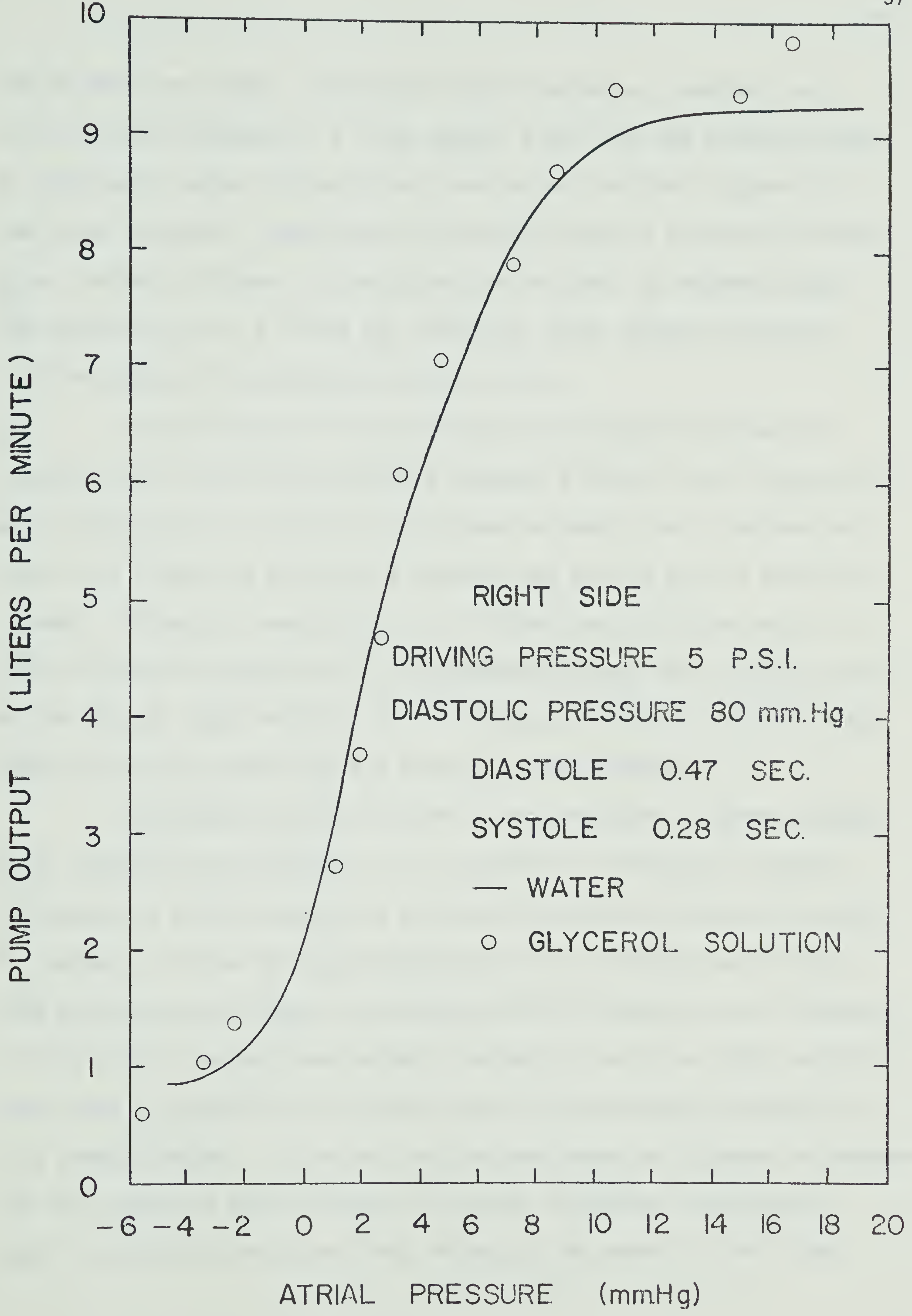


FIG. 4.2 COMPARISON OF WATER & GLYCEROL SOLUTION

was 80 beats per minute. Holding all other parameters constant, the atrial pressure (Appendix D) was reduced slowly and the function curve of ventricular output versus atrial pressure was obtained (Figure 4.3). The curve is readily identified as having the shape of a normal Starling's curve for the left heart differing only in the level of maximum output. The sensitivity of 1.2 liters per minute per mm.Hg compares favorably with the slope of the natural Starling's curve.

A similar test of the right side with diastolic pressure of 30 mm.HG. and 4 psi driving pressure produced a similar curve (Figure 4.4) with sensitivity of 1.25 liters per minute per mm.Hg. and a maximum output of 9.3 liters per minute at a diastole and systole of 0.47 and 0.28 seconds. Although a sensitivity of 1.2 liters per minute per mm.Hg. is ideal for the left ventricle it is considerably lower than the sensitivity of the natural right ventricle of 4.3 liters per minute per mm.Hg. Parameters affecting sensitivity are discussed under section 4.2.

By pumping with the left and right ventricles in series through their respective test chambers, it is possible to examine the response to changes in atrial pressure in a situation similar to that which occurs in the body. If the driving pressures are set to provide equal outputs from both sides the outputs can be controlled by adjusting atrial pressure. If left atrial pressure were suddenly reduced to zero, the right ventricle would pump into the left atrium until equilibrium was again reached now at a reduced output. If the left atrium experienced an increase in pressure the left ventricle would increase its output increasing the pressure level in the right atrium and thus increasing the output of the right

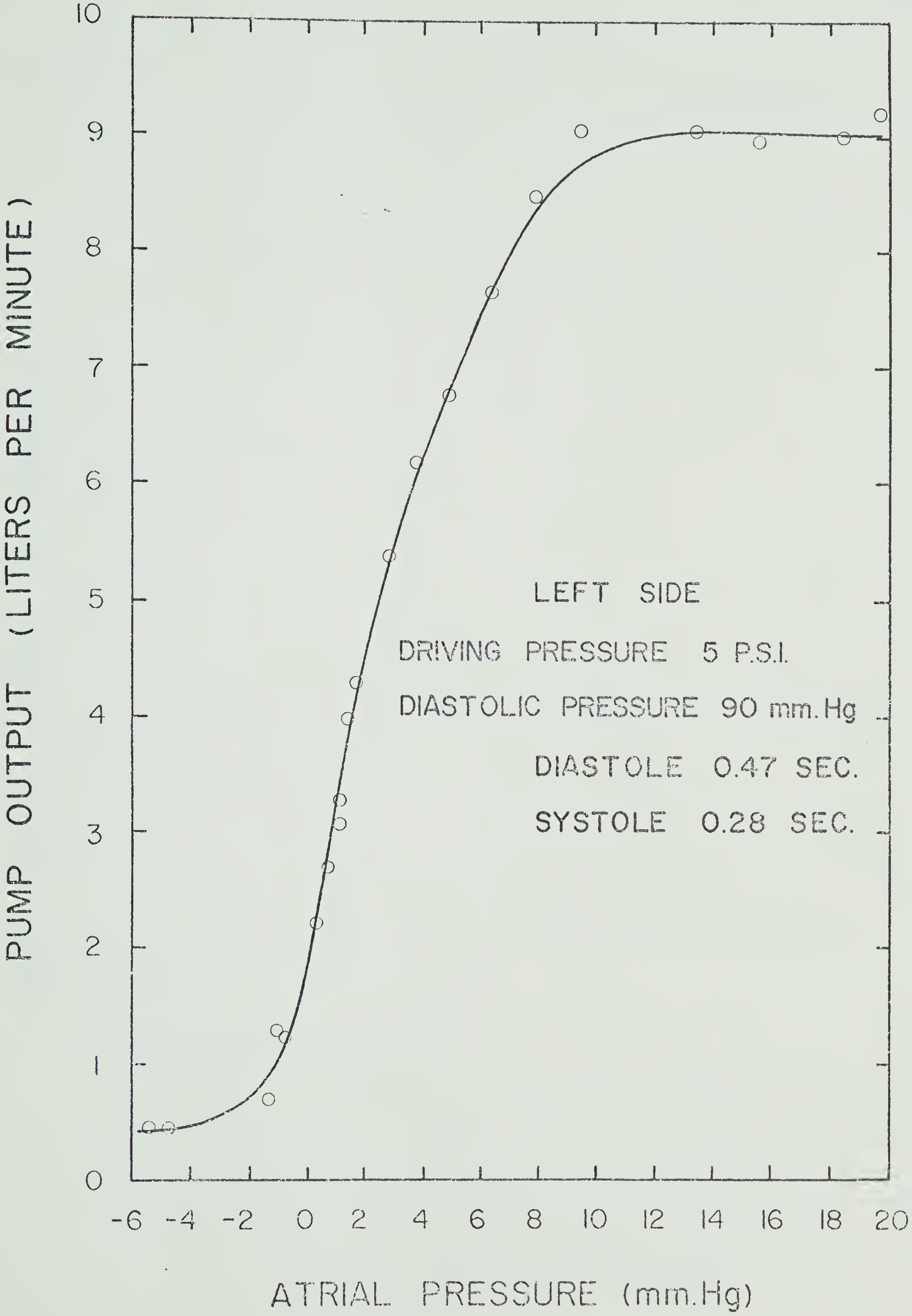


FIG. 4.3 VARIATION OF ATRIAL PRESSURE

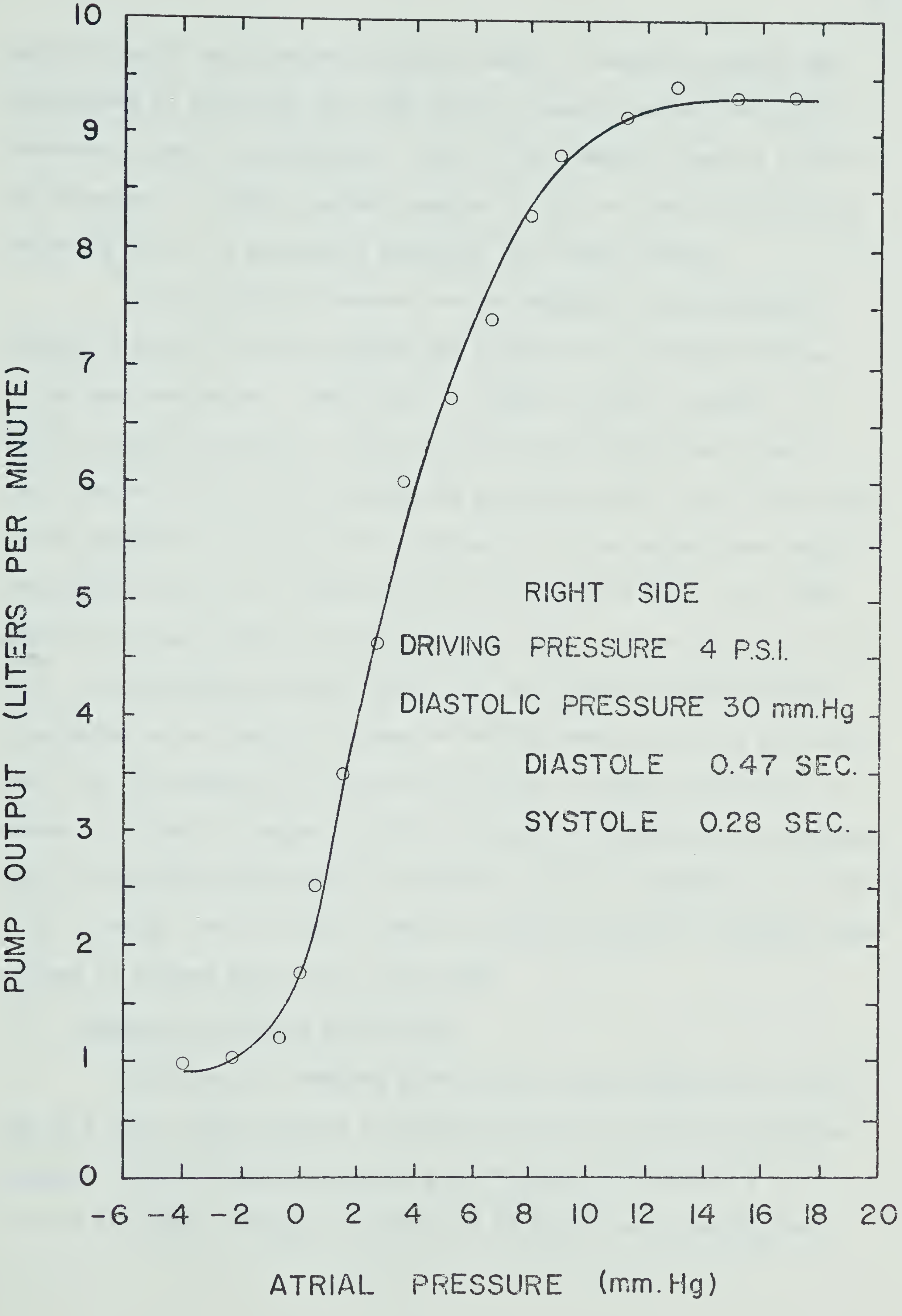


FIG. 4.4 VARIATION OF ATRIAL PRESSURE

ventricle until equilibrium was again reached. Identical effects are encountered by adjusting the right atrial pressure causing left atrial pressure to come to equilibrium. This is the intrinsic control of output necessary to prevent unequal pumping of the left and right sides of the heart which, as previously mentioned, has fatal effects.

If the driving pressures are not adjusted to provide equal outputs at similar inlet pressures the system will reach equilibrium by the same mechanism ; sensitivity of output to atrial pressure. If the left ventricle had too low a driving pressure the higher output of the right ventricle would increase the pressure level in the left atrium at the expense of its own atrial pressure until the outputs were equal. The opposite occurs for ventricular driving pressure that is too high, lowering its own output and increasing the output of the other ventricle. With this interaction between ventricles, the output of both sides may be adjusted up or down by a change in driving pressure of only one side. Here lies the necessity for artificial hearts to exhibit sensitivity of change in output to changes of atrial pressure of physiological magnitude. Since the maximum physiological variation of atrial pressures is only about 15 to 20 mm.Hg. the artificial ventricle must be capable of changing from maximum to minimum output over this range.

4.1.2 Response to Varying Heart Rate

The effect of changing heart rate is best examined by varying one at a time; either systole or diastole from its previously described optimum. With driving pressure at 5 psi for the left ventricle and 4 psi for the right, diastolic pressure at 80 mm.Hg. and 30 mm.Hg. and

atrial pressures at 10 mm.Hg., systole was first held constant at 0.28 seconds and diastole varied from 0.05 seconds to 3.8 seconds. Clearly, (Figure 4.5) the optimum output is obtained with a diastole of about 0.47 seconds. By holding diastole constant at 0.47 seconds and varying systole from 0.1 to 1.25 seconds optimum output occurs at a systole of 0.28 seconds (Figure 4.6). Clearly, the optimum diastole and systole is approximately 0.47 and 0.28 seconds giving a systole of 37% of cycle. By converting systolic and diastolic duration to beats per minute the optimum heart rate is about 80 beats per minute (Figure 4.7 and 4.8) for both the left and right ventricles. Figures 4.7 and 4.8 show that ventricular output is more sensitive to variation of systole than to variation of diastole, but very sensitive to both.

The shapes of the varying systole and diastole curves are as expected since too short a pulse causes incomplete filling of the sac during diastole and incomplete evacuation of the sac during systole. Too long a pulse introduces idle periods after complete filling of the sac during diastole and following complete evacuation of the sac during systole. The optimum diastole and systole provides a pumping action where systole begins the instant the sac is completely filled and ends when the sac has evacuated about 75% of its contents. Longer periods of systole decrease efficiency by forcing the sac up against its opposing inner surface and against the valves, developing folds which form small pockets of fluid and tend to require a considerably longer diastole to refill: such effects in vivo are clearly undesirable.

The natural heart at a rate of 75 beats per minute exhibits a systole of 0.3 seconds or 37 to 38% of the total time of one cycle. The

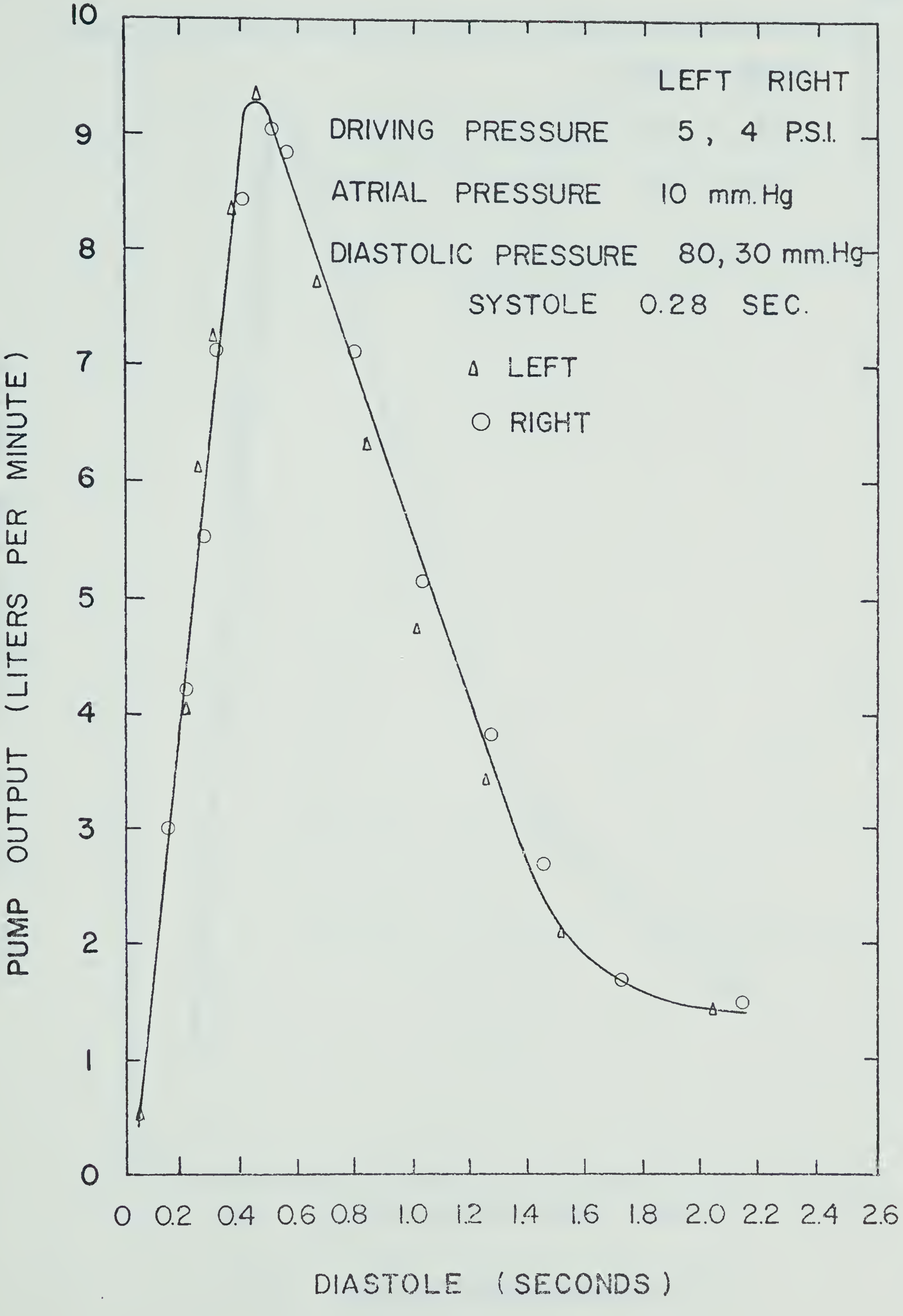


FIG. 4.5 EFFECT OF VARYING DIASTOLE

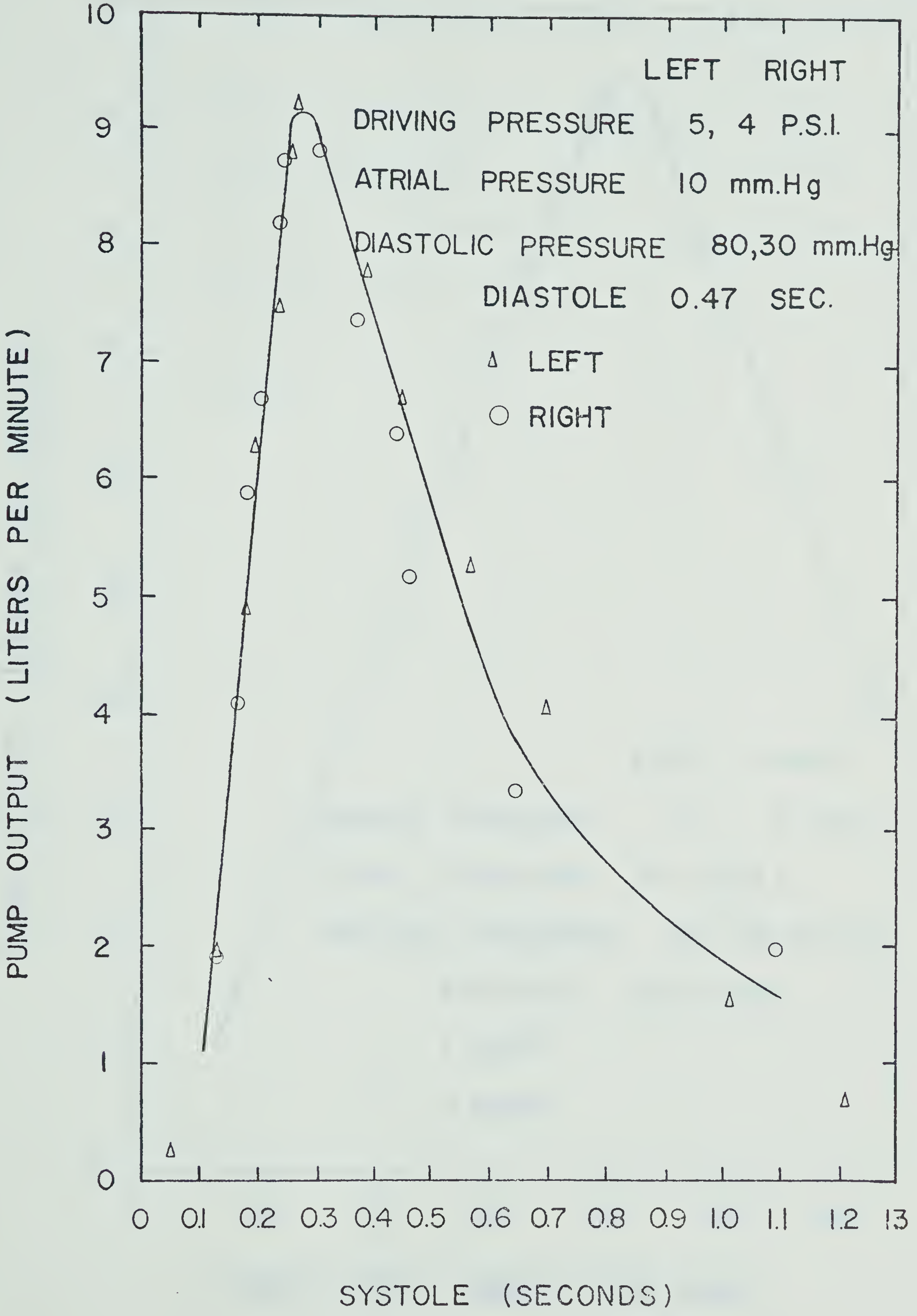


FIG. 4.6 EFFECT OF VARYING SYSTOLE

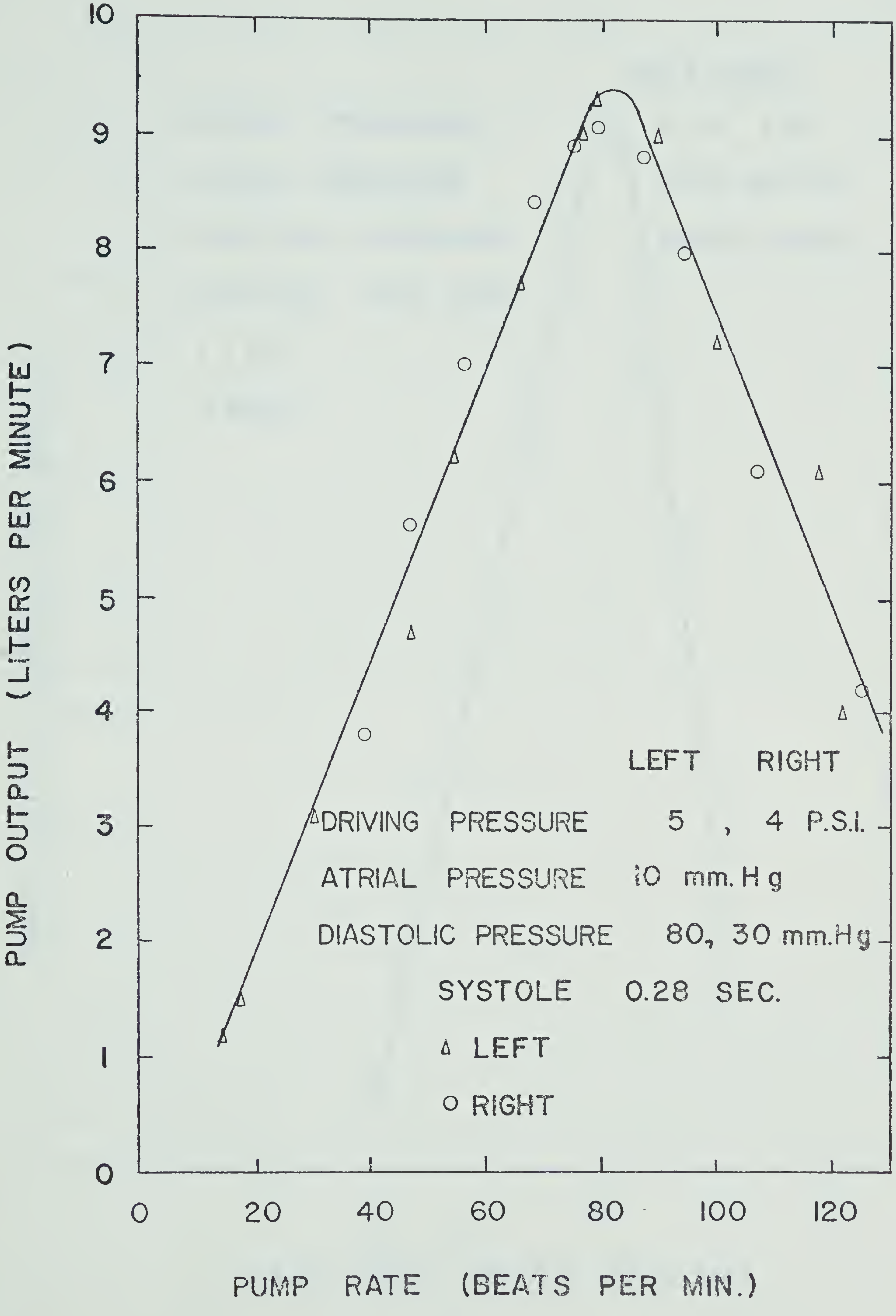


FIG. 4.7 OPTIMUM PUMP RATE — VARIABLE DIASTOLE

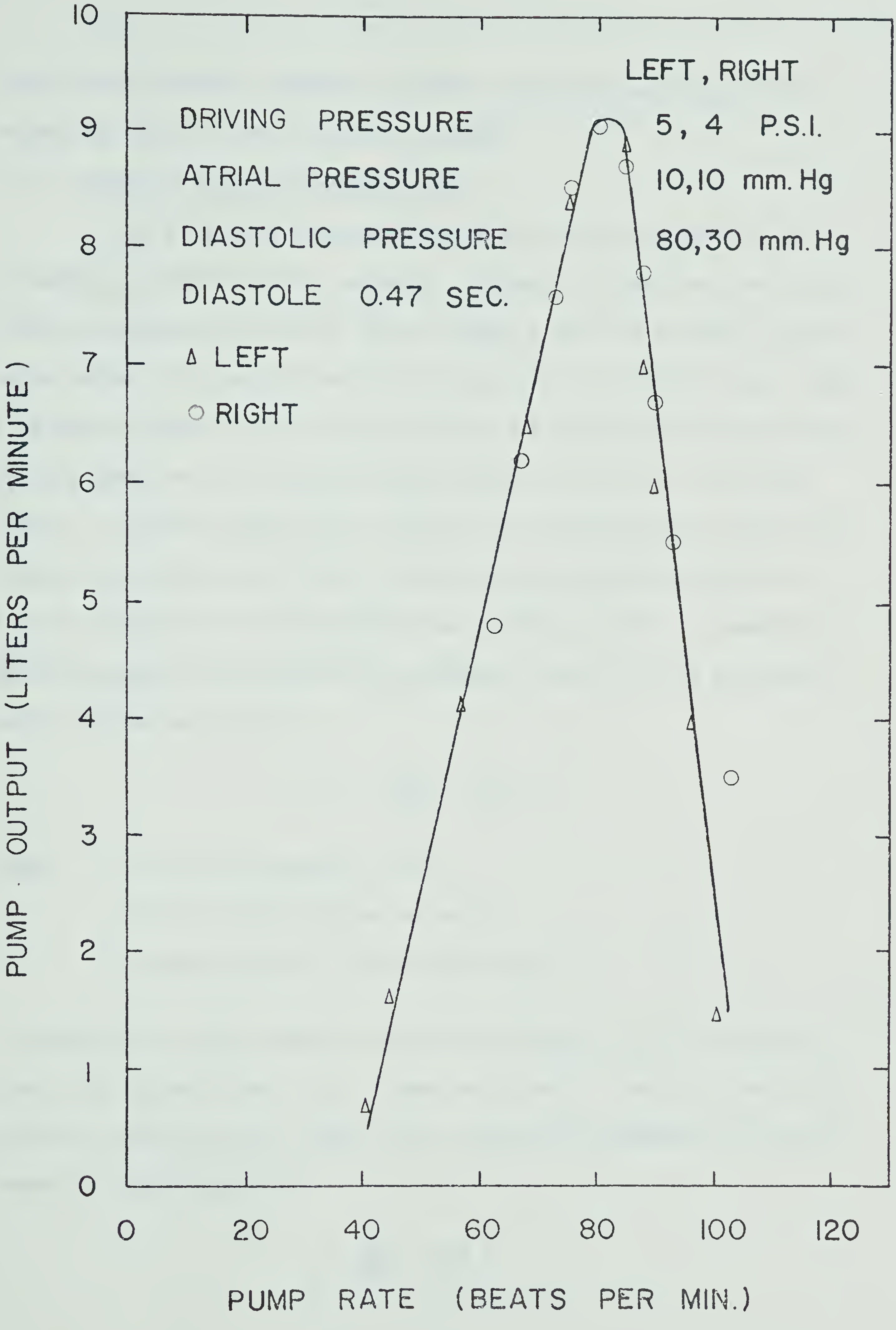


FIG. 4.8 OPTIMUM PUMP RATE — VARIABLE SYSTOLE

pump tested therefore compares favorably with the natural heart with respect to systolic and diastolic duration.

4.1.3 Response to Varying Output Load

The effect of increased diastolic or back pressure is only to demand a greater driving pressure. Figure 4.9 shows that the left ventricle displays an initial loss of about 1 psi for no load, and requires about 1 psi per 55 mm.Hg. back pressure to initiate flow. After flow begins there is an increase of about 4.5 liters per minute per psi driving pressure to a maximum output between 7.5 and 9.5 liters per minute. Pressures greater than required for maximum output cause output to drop sharply due to the inefficiency previously mentioned i.e. extreme evacuation of the ventricle sac during systole. An empirical equation approximating the driving pressure required for a particular back pressure and flow is

$$P = 1 + \frac{A}{55} + 0.22\ B$$

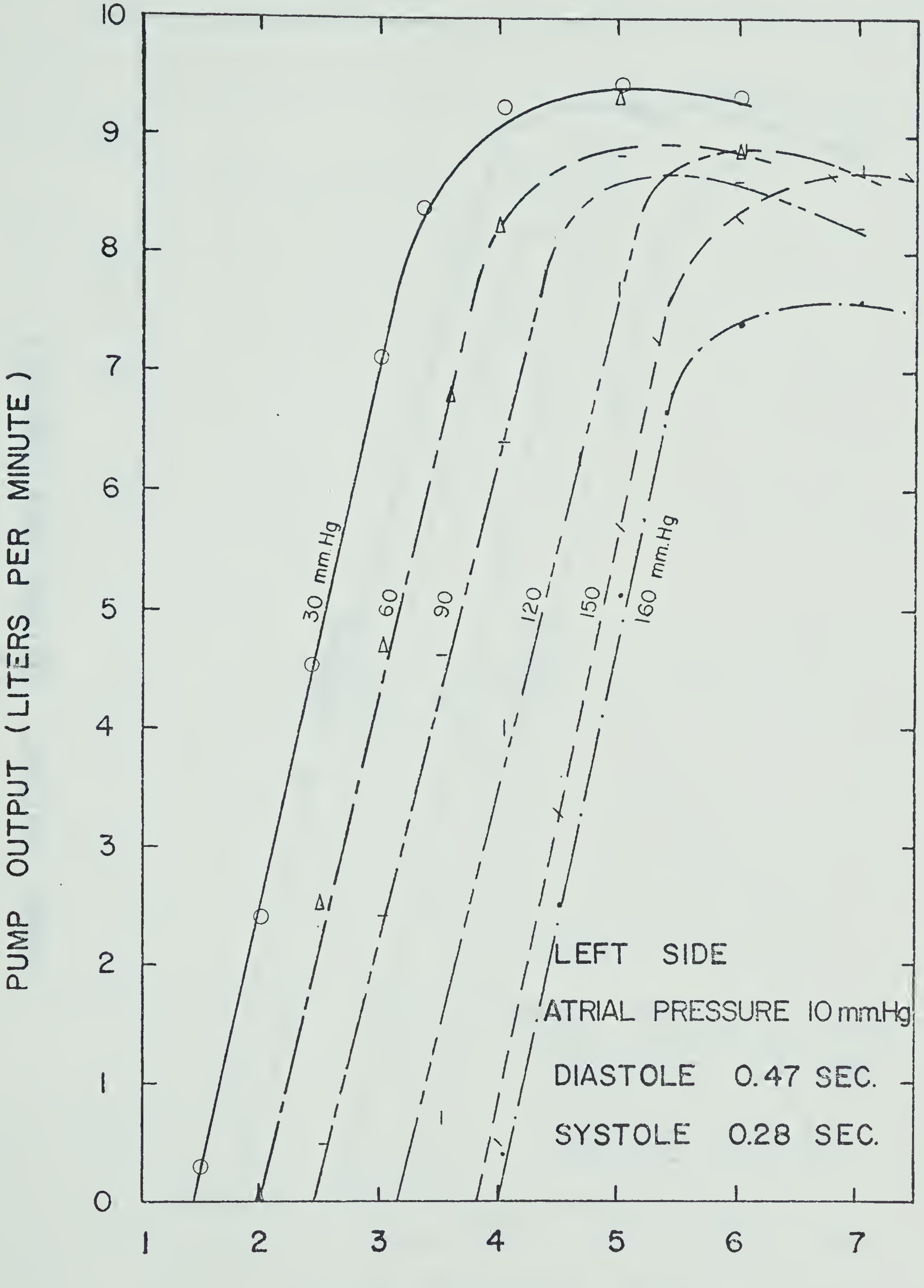
where P = driving pressure in psi

A = diastolic pressure in mm.Hg.

B = pump output in liters per minute.

This equation yields outputs to within an accuracy of 1/2 liter per minute for outputs from 0 to 8 liters per minute. The right ventricle exhibits similar curves (Figure 4.10) yielding an expression for estimated driving pressure of:

$$P = \frac{A}{55} + 0.28\ B$$



EFFECT OF VARYING DIASTOLIC PRESSURE

FIG. 4.9 AND DRIVING PRESSURE

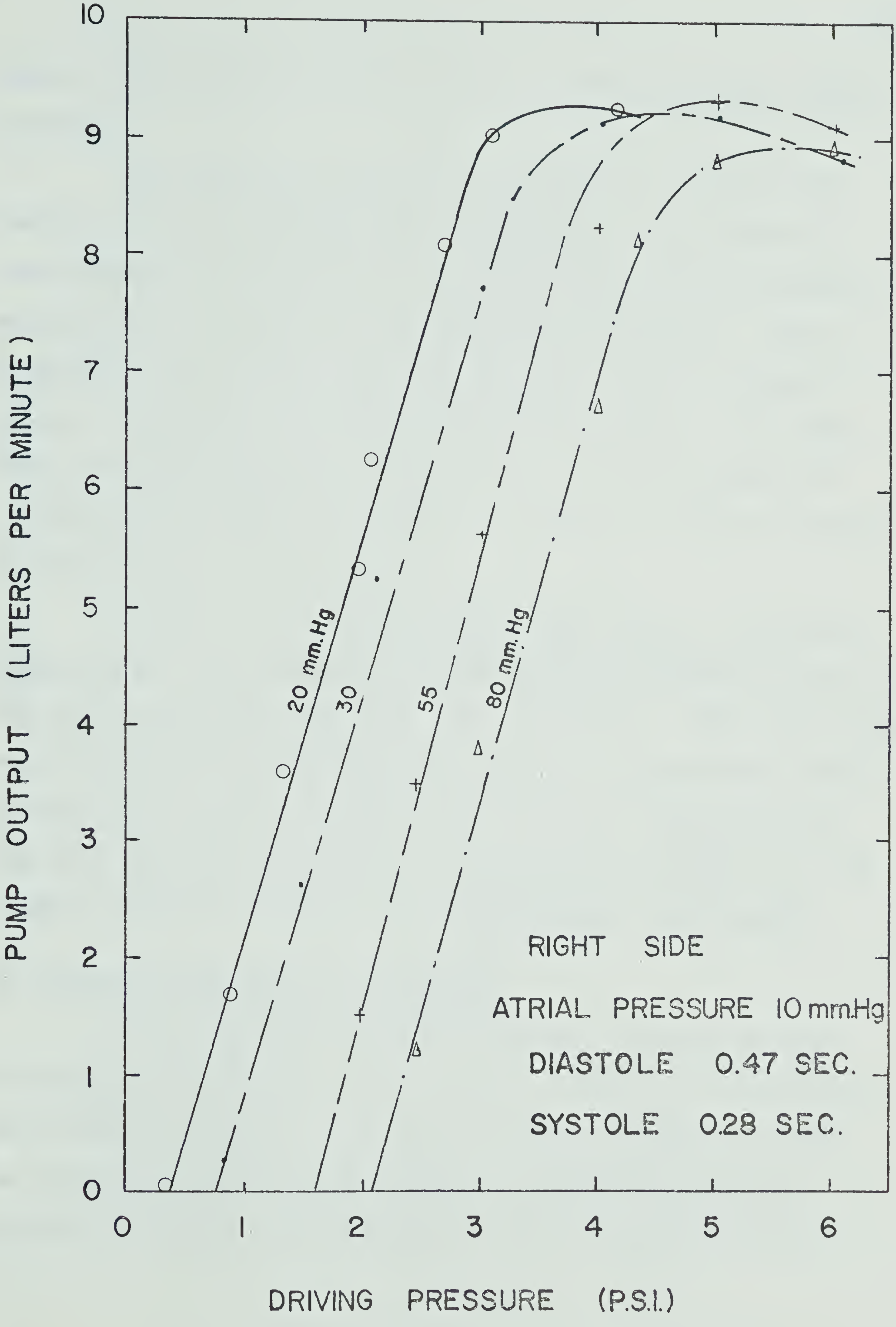


FIG. 4.10 EFFECT OF VARYING DIASTOLIC PRESSURE AND DRIVING PRESSURE

which is also accurate to within 1/2 liter per minute from 0 to 8 liters per minute.

Back pressure has little or no effect upon the shape of the Starling curve as is evidenced by the superimposing of two curves for the right ventricle (Figure 4.11), one with a back pressure of 30 mm.Hg. and the other of 80 mm.Hg., all other parameters being equal. This is an important consideration since with the natural heart an increase in output is accompanied by an increase in diastolic pressure. This means that when considering pump output curves under in vivo conditions the driving pressure could be increased as flow rate was increased to maintain the shape of the Starling's curve.

In the case of an immoblized experimental animal, the diastolic pressure would likely remain fairly constant since the demand for blood and thus atrial pressure and pump output would be constant. Under such conditions the driving pressure could be adjusted manually. If experimental animals were mobilized, requiring changing blood flow rates, a mechanism would have to be developed which would vary driving pressure automatically with changes in diastolic pressure if auto regulation were to be complete.

4.2 Starling's Regulation - Variable Rate

It is of interest to examine the effect of varying rate upon the response of the pumps to atrial pressure. Since the filling pressure has no effect on systole or vice versa, the rate is changed by altering the diastole and keeping systole constant. By maintaining diastolic pressure at 30 mm.Hg., driving pressure at 4 psi and systole at 0.28

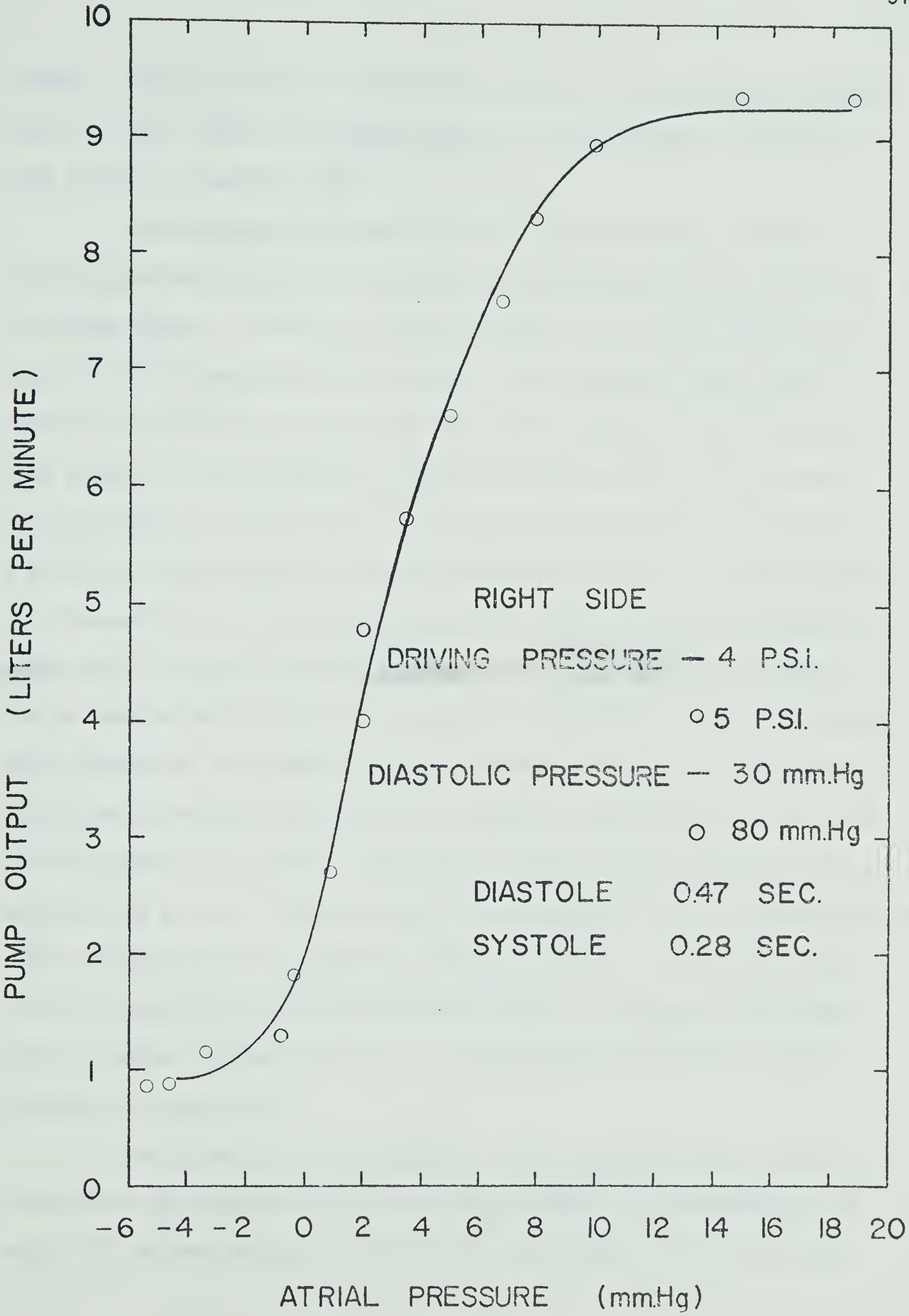


FIG. 4.11 COMPARISON OF STARLING'S CURVES AT DIFFERENT DIASTOLIC & DRIVING PRESSURES

[illegible]

seconds, diastole was varied from 0.34 seconds to 0.12 seconds to produce plots of right ventricular output against filling pressure, the same as done before for constant rate.

From the curves (Figure 4.12) it is obvious that a shorter diastole (faster heart rate) produces a low sensitivity but an increase in maximum output. A longer diastole (slower heart rate) yields a high sensitivity but reduced maximum output. Long diastole creates high sensitivity to filling pressures at low atrial pressure since it may be long enough to allow complete filling of the ventricle. At increased atrial pressure the bag fills in a fraction of the diastole introducing a period of idle time with no further effect on output. As the diastole is decreased so is the sensitivity, but the output range is consequently increased. The sensitivity is reduced by the less complete filling of the sac and maximum output is increased by a reduction of the idle period during diastole. A further decrease in diastole reduces the sensitivity but increases maximum output only at very high atrial pressure since the filling period is so short. The optimum output for each setting occurs when the bag is just filled at the end of diastole. There is a possibility that different valves may produce different results. Valves exhibiting a large regurgitation may reach maximum output at a slower rate whereas highly competent valves may not. The valve type used for this test is discussed in section 4.4.

The curve for short diastole is not acceptable due to its low sensitivity and demand of atrial pressures higher than physiological to attain its maximum output. The curve of long diastole has a favorably

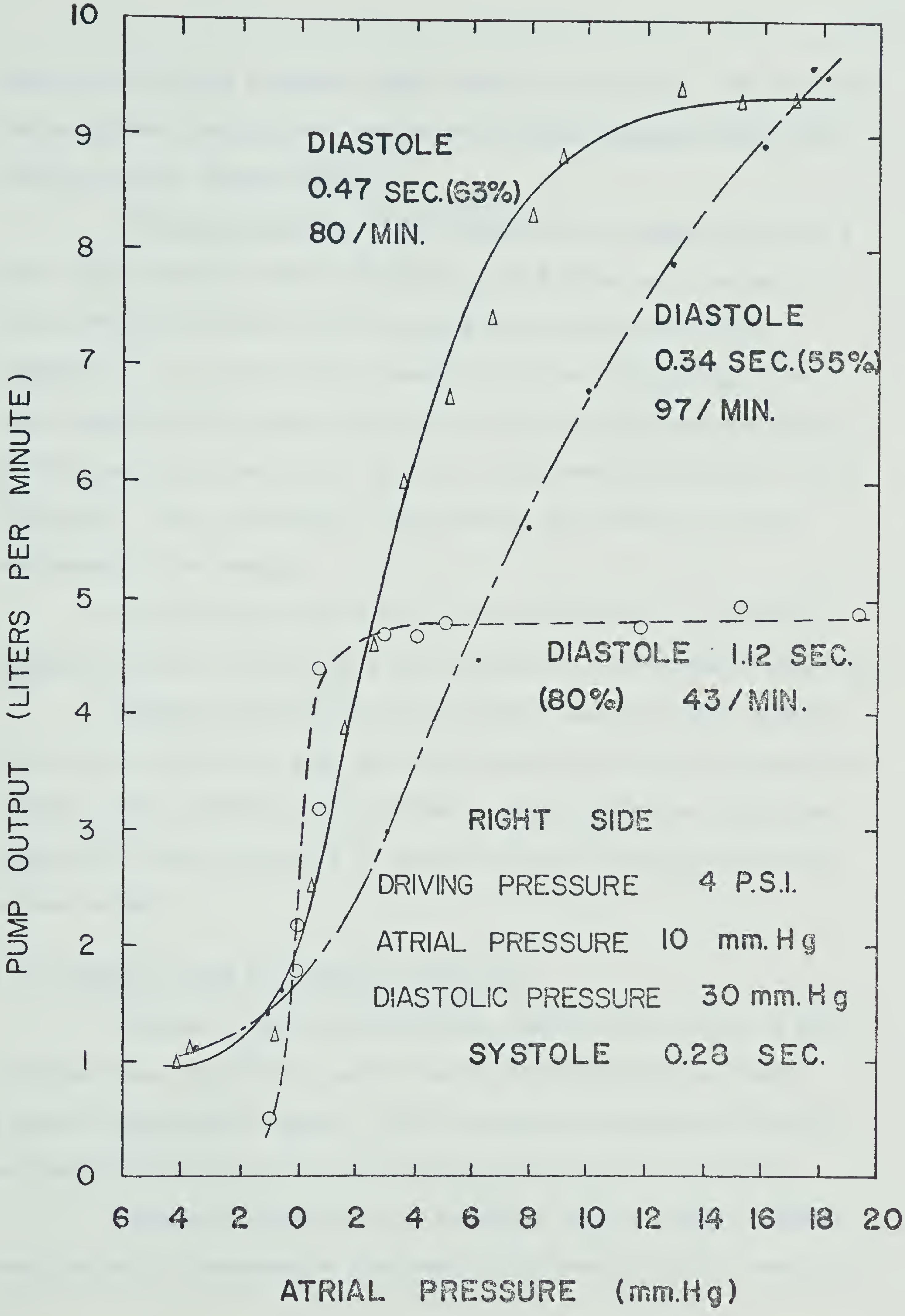


FIG. 4.12 VARIATION OF ATRIAL PRESSURE & RATE

[illegible]

high sensitivity but a maximum output that may be too low. The curve for previously described optimum systole and diastole has good sensitivity and satisfactory maximum output.

Although the natural right ventricle has a sensitivity of 4.3 liters per minute per mm.Hg. rather than 1.2 for the left, necessity for an artificial heart to have the same has not been established (Appendix E). If it were found necessary for the sensitivity of the right ventricle to be greater than 1.2 it could be increased to perhaps 5 liters per minute per mm.Hg. but with a considerable sacrifice of maximum output. Such a limitation could possibly be removed by further development of the design.

A similar test of the left ventricle (Figure 4.13) produced comparable results with only a slight reduction of the maximum sensitivity.

Although the effect of variable rate upon the output function curve is of interest the pump and control mechanism has been designed to function under constant rate conditions. The variable rate study does however facilitate the choice of optimum rate and thus sensitivity and maximum output.

4.3 Comparison with Physiological Pressures

Although it has not been proven essential to identically mimic the output wave form of the natural heart it is necessary to create pressures within physiological limits to provide an adequate flow while not damaging blood by virtue of excessive pressures and velocities.

Since the circulations are nominally passive elastic networks providing only a impedance to the heart, it is possible with a ventricle

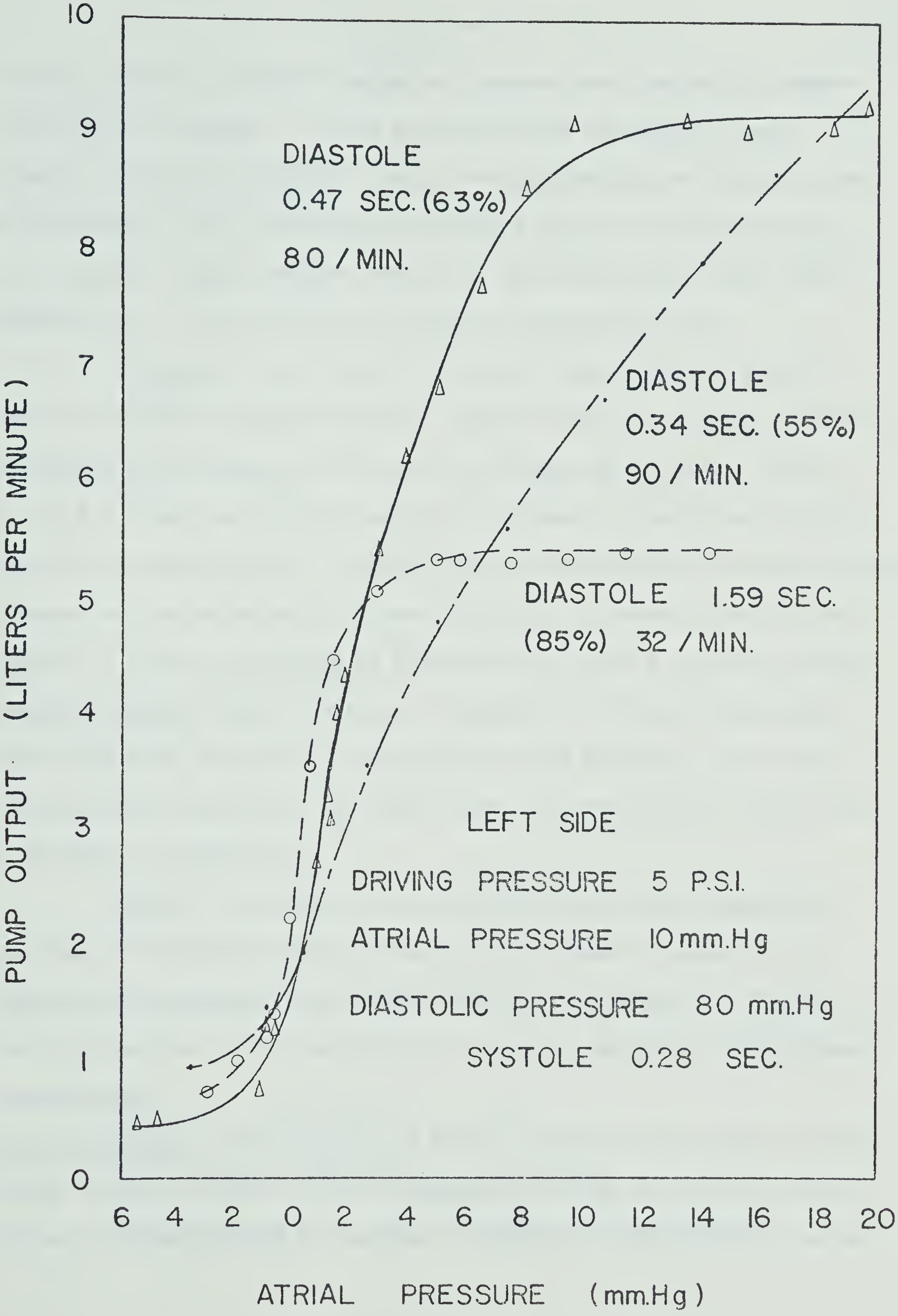


FIG. 4.13 VARIATION OF ATRIAL PRESSURE & RATE

[illegible]

sac type design to simulate the output pressure wave form with a reasonable degree of accuracy. It has been shown that variation of back pressure, within physiological limits, does not change the function curve of the output of the pump but only demands a change in driving pressure. It is for this reason pressure traces for different output loads differ primarily only in a scaling up or down of a common wave form.

Pressure traces (Figure 4.14 to 4.21) were taken at about 70 beats per minute at optimum systolic diastolic ratio, a pulmonary arterial resistance of 25 mm.Hg. and a systemic resistance of 80 mm.Hg. An output of 8.5 liters per minutes roughly corresponds to conditions of light work for an average adult. Systolic pressure is adjustable through driving pressure and was selected to be about 60 mm.Hg. (pulmonary) and 130 mm.Hg. (aortic). These tracings may be compared with Figure 4.22 which displays pressure tracings from a healthy dog (Appendix F). Due to the variable conditions under which these measurements could be taken in the animal the absolute pressures are not significant, only the profile or wave form is intended for comparison.

Pressure recordings from within the pump display damped overshooting of the recording pen following rapid pressure changes. Suggestions of the cause of this effect are given in Appendix G. The following discussion of the recordings will exclude the effect of the damped overshooting.

Atrial Pressure - The recordings of atrial pressure in the pump (left and right) (Figure 4.14 and 4.18) are marginally similar to the dog tracing (Figure 4.22) exhibiting an increase in pressure at the beginning and end

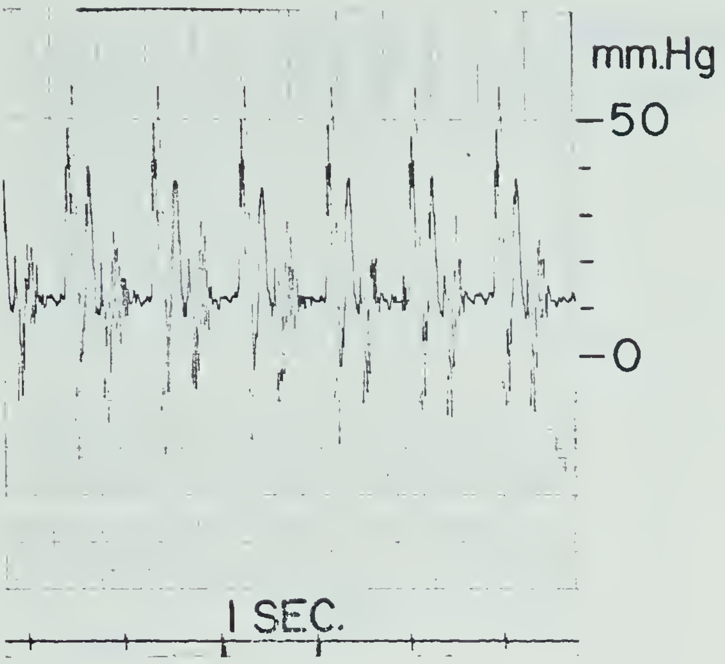


FIG. 4.14 RIGHT ATRIUM

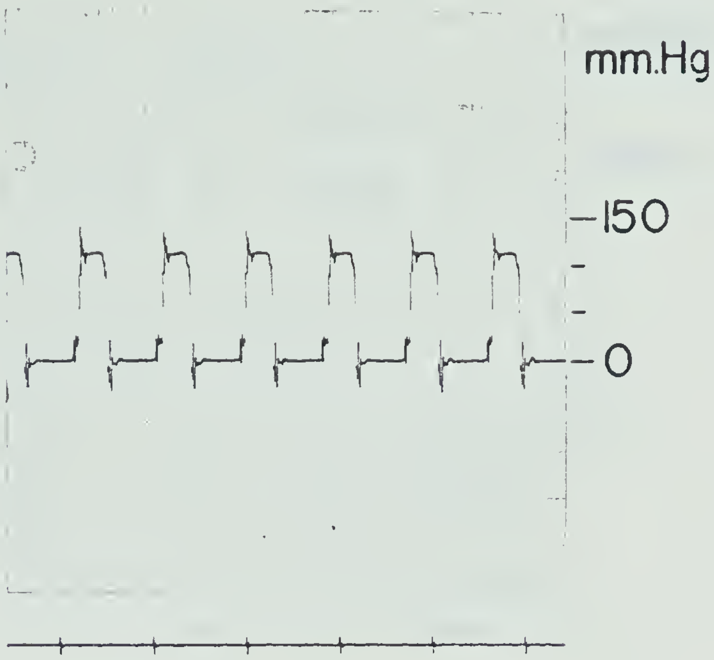


FIG. 4.15 RIGHT VENTRICLE

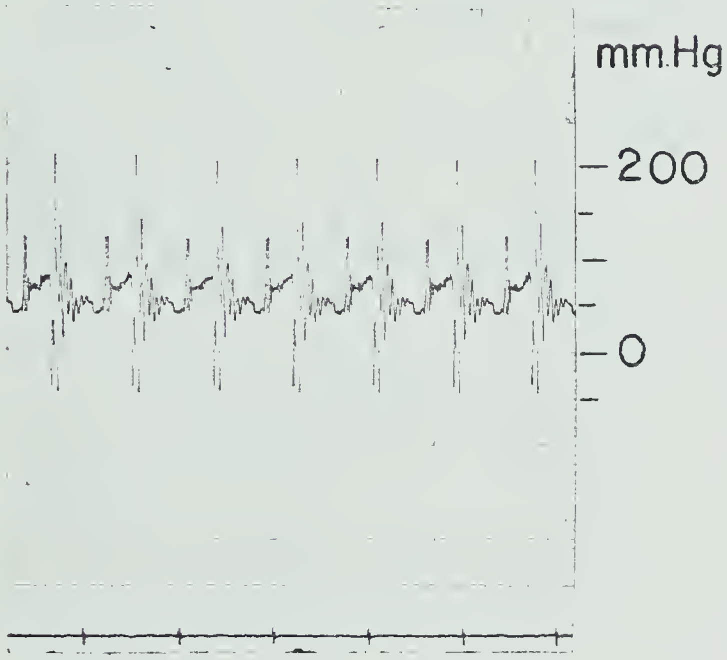


FIG. 4.16 PULMONARY ARTERY

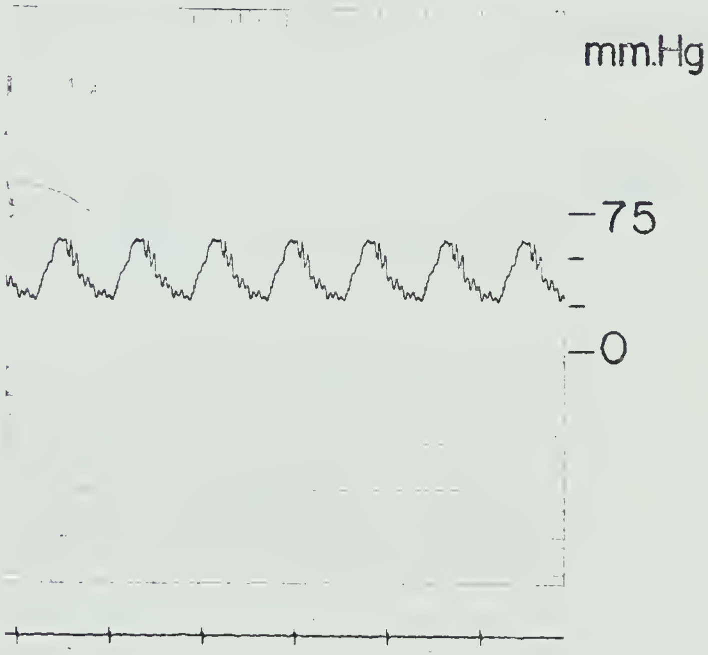


FIG. 4.17 PULMONARY ARTERY
(TEST CHAMBER)

DRIVING PRESSURE 3 P.S.I.

DIASTOLIC PRESSURE 25 mm.Hg

PUMP OUTPUT 8.5 LITERS PER MINUTE

FIGS. 4.14-4.17 PUMP PRESSURES - RIGHT SIDE

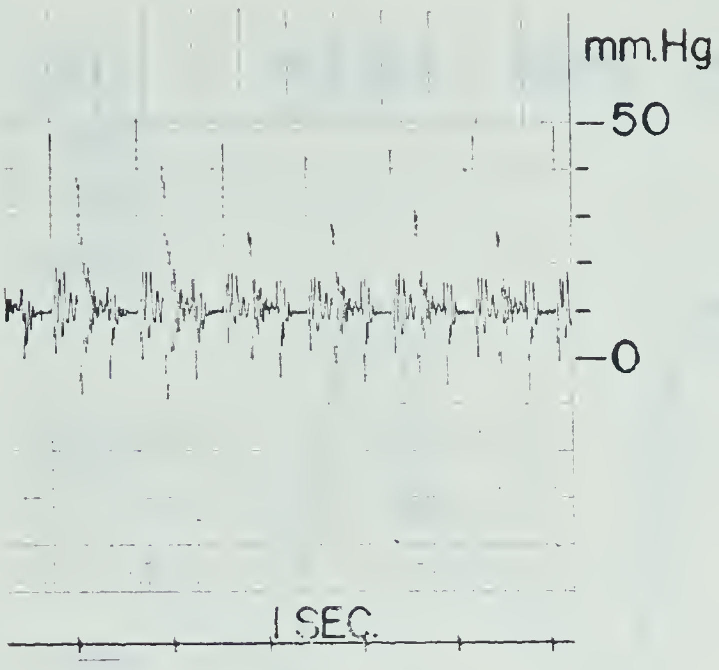


FIG. 4.18 LEFT ATRIUM.

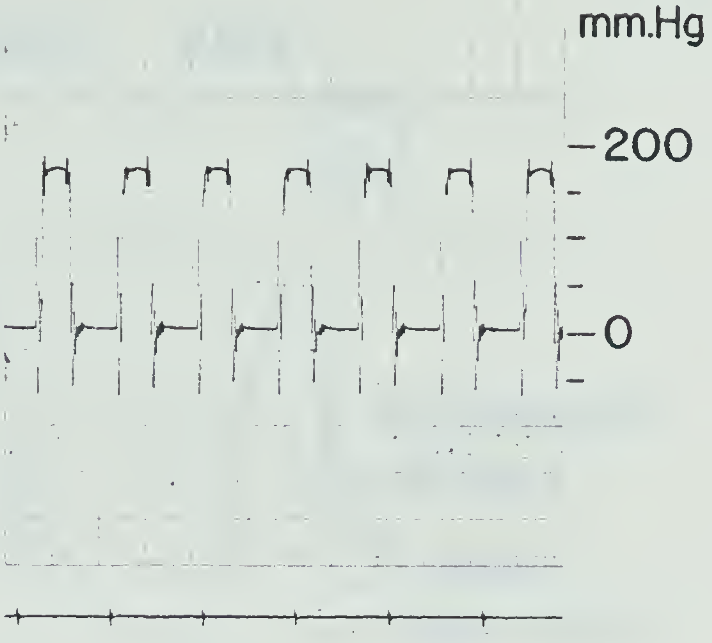


FIG. 4.19 LEFT VENTRICLE

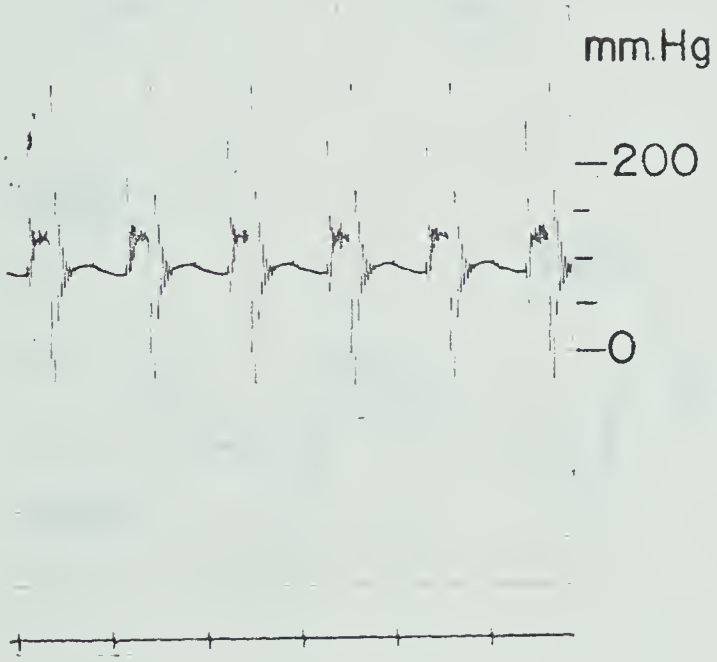


FIG. 4.20 AORTIC ARTERY

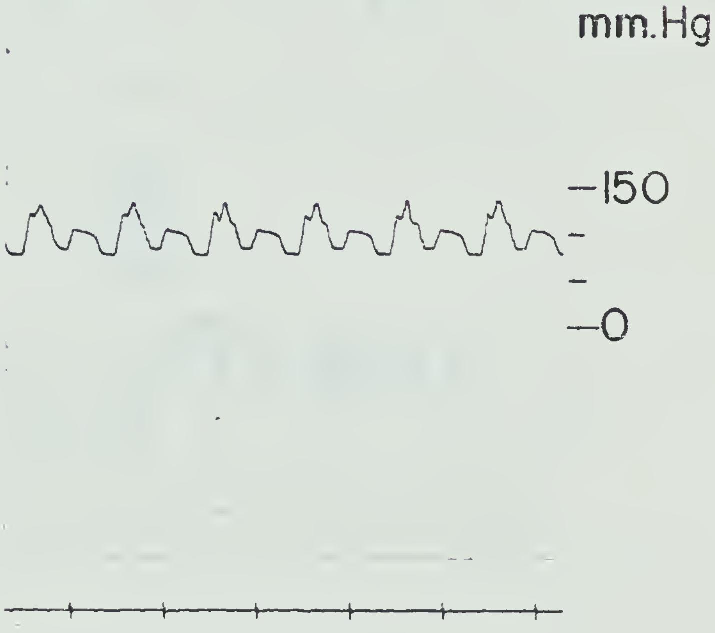


FIG. 4.21 AORTIC ARTERY
(TEST CHAMBER)

DRIVING PRESSURE 5 P.S.I.

DIASTOLIC PRESSURE 80 mm.Hg

PUMP OUTPUT 8.5 LITERS PER MINUTE

FIGS. 4.18-4.21 PUMP PRESSURES – LEFT SIDE

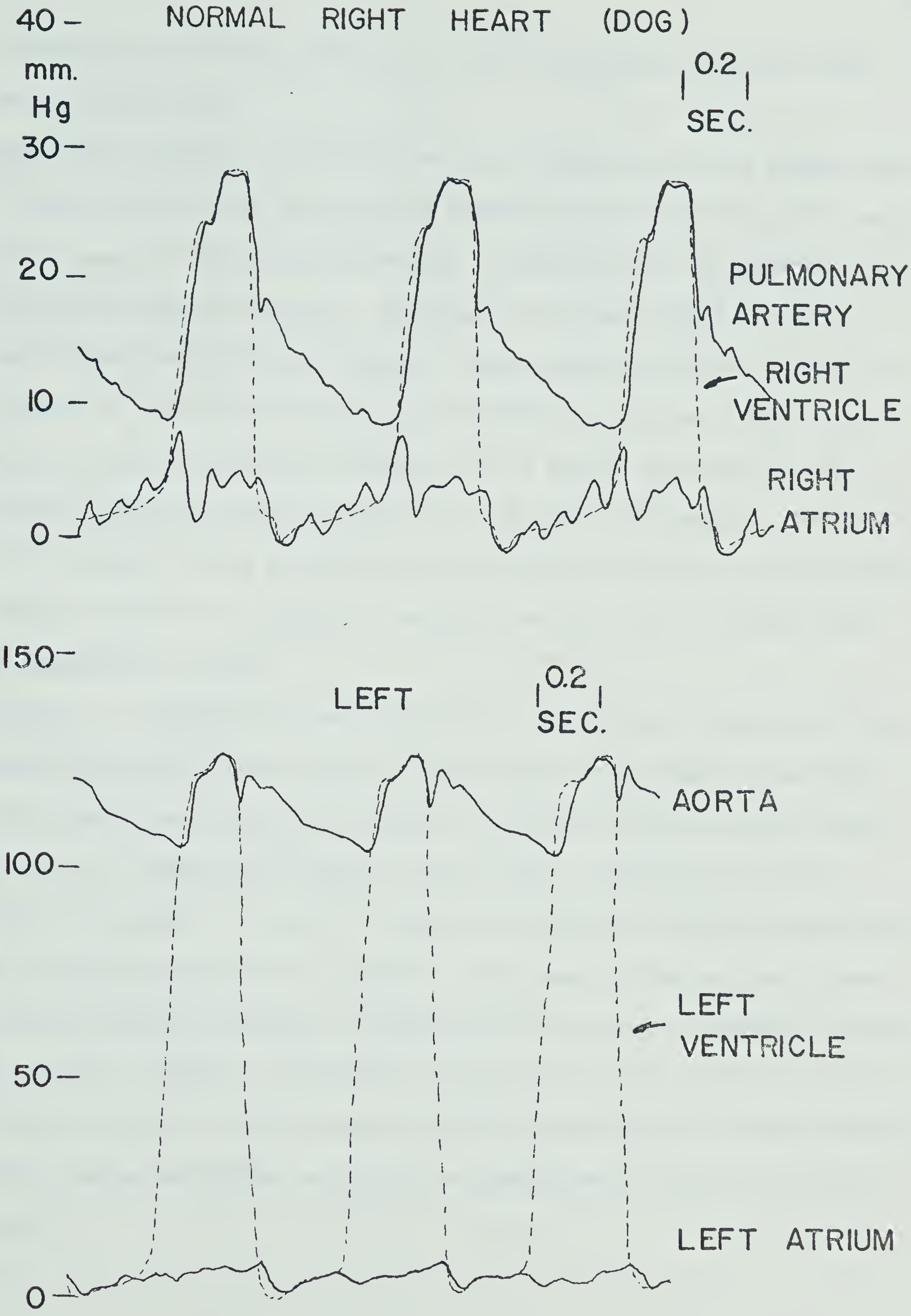


FIG. 4.22 NORMAL CARDIAC PRESSURES (24)

of systole due to valve action and slight regurgitation from the high pressure ventricle.

Ventricular Pressure - Both left and right ventricles record a wave form (Figure 4.15 and 4.19) very closely resembling that of the dog with very steep slopes at the beginning and end of systole and a flattening during mid-systole and mid-diastole. The pumps do however demand a systolic ventricular pressure about 40 mm.Hg. above systolic arterial pressure in contrast to the natural heart whose ventricular pressure is only a few mm.Hg. higher than arterial pressure. This may be attributed to the constant diastolic pressure property of the mock circulation. The pump will initiate flow at a ventricular pressure only slightly above arterial pressure, but for an adequate flow rate, the ventricular pressure must be considerably higher.

Arterial - Pulmonary and aortic arterial pressures were measured at two locations for each side; one within the pump directly down-stream from the outlet valves (Figure 4.16 and 4.20) and one within the test chamber several cm. downstream (Figure 4.17 and 4.21). Pulmonary and aortic pressures measured at the first location display the familiar interference at the beginning and end of systole. Measurements from the down stream position are more readable, not exhibiting the spikes. Pulmonary pressure is 60 mm.Hg. systolic and 25 mm.Hg. diastolic tracing a curve very like that of the dog. Aortic pressure is 130 mm systolic and 75 mm.Hg. diastolic with accentuated notches recording the opening and closing of the aortic valve.

4.4 Heart Valves

In the pumping unit four mechanical valves are required to produce unidirectional blood flow, one inlet valve and one outlet valve for each ventricle. They are passive one-way check valves.

The mechanical requirements are that the valve should be large enough to prevent stenosis and close quick enough to prevent insufficiency. It should be so shaped as to cope with the unique rheological characteristics of the blood (i.e. blood is a non-Newtonian colloidal solution)[20] in order to maintain a laminar flow and to reduce shearing effects which lead to turbulence, eddy formation, and thrombosis. The contact surfaces should be minimal to reduce hemolysis of the formed elements of the blood. The valves should be constructed of materials which are non-carcinogenic, non-antigenic, non-electrolytic, non-toxic, non-hemolytic, and clot repellant. The requirements of valves in the mechanical heart are not as stringent as for the physiological heart. They may be larger and therefore more efficient. There exists a vast variety of commercially available prosthetic heart valves employing balls, discs, flaps, leaflets etc. During the project, pumps were constructed incorporating several different types of valves.

The first valves experimented with were Hammersmith mitral valve prostheses reproduced by Kolff's laboratories in Salt Lake City for their own use in artificial hearts. The design consists of a ring from which a trap door is suspended by three short legs (Figure 4.23). The whole structure is molded of polypropylene, a material which is biologically inert. The sizes used were 19.3 mm. orifice diameter for outlets and 22.5 mm.

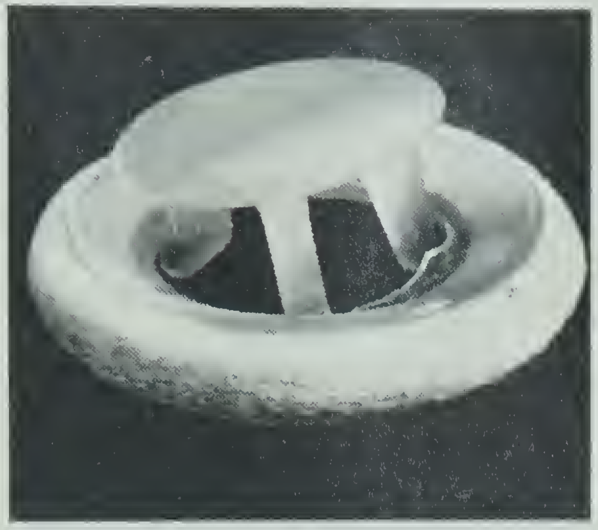


FIG. 4.23 HAMMERSMITH

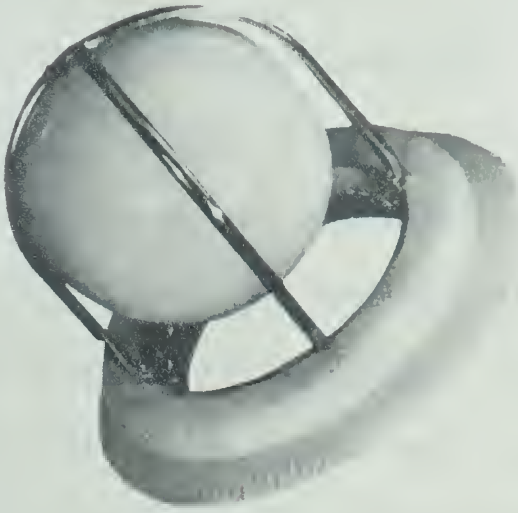


FIG. 4.24 STARR-EDWARDS

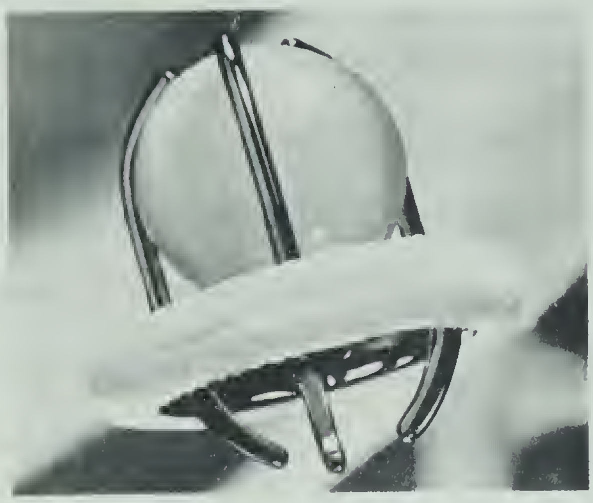


FIG. 4.25 SMELOFF-CUTTER

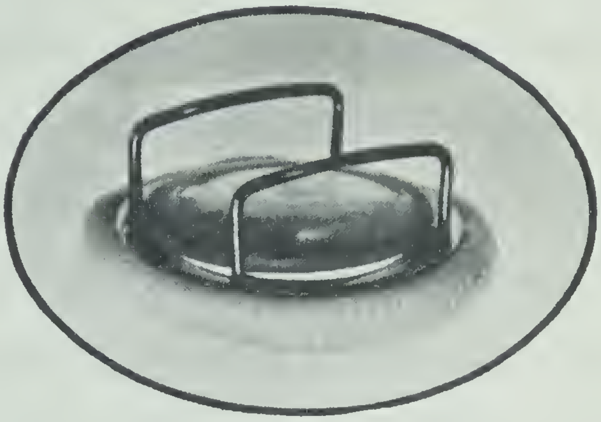


FIG. 4.26 KAY-SHILEY

FIGS. 4.23-4.26 PROSTHETIC HEART VALVES

for the inlets. These valves produced very poor results due to occasional sticking in the open position particularly at the outlet locations. Output was inconsistent and a very low sensitivity on the output versus atrial pressure plot was achieved with a maximum output of about 6.5 liters per minute. The sticking phenomenon was perhaps peculiar only to the non-original valves but it did render them unsatisfactory. The valve does have the advantagesof a low profile and therefore short ventricular intrusion and comparatively low cost. It has been temporarily removed from sale by the original manufacturer due to failure of legs following long term service (several years).

The next valves to be incorporated were Starr-Edwards Model 6120 mitral valve prostheses. The 6120 prosthesis consists of a polished Stellite 21 cage containing a silicone rubber ball (Figure 4.24). Orifice sizes of 19 and 20 mm. were used. The inlet valve stuck in the closed position at atrial pressures of less than 10 to 15 mm.Hg. Above this pressure the valves appeared to operate smoothly and consistently with a maximum output of 9 liters per minute, but since 15 mm.Hg. atrial pressure is close to the maximum encountered in the body, the valves were unsatisfactory. The flexible ball seemed to stick in the seat as a result of the rapidity of closing as the pump changed from diastole to systole. This type of caged ball has a notable disadvantage of large volume and particularly great ventricular intrusion interfering with the action of the sac.

The next valves used were two 19 mm. orifice diameter Smeloff-Cutter mitral valve prostheses. It is a double cage ball design which,

unlike the Starr-Edwards valve, allows a larger effective orifice diameter since the orifice is larger than the ball (Figure 4.25). The ball passes one half way through the orifice and seats on the lower cage rather than on the orifice. This design reduces sphere volume by 50% and greatly increases effective orifice area. This valve tested in only one left side produced excellent characteristics with a maximum output of 8.5 liters per minute and a sensitivity of 1.2 liters per minute per mm.Hg. The only disadvantage to this valve was its larger intraventricular intrusion and occasional interference with the ventricle sac during systole at high output.

Finally, 19 and 22 mm. orifice Kay-Shiley disc valves were used in one complete pump. The valve consists of a silastic disc and a Stellite metal cage (Figure 4.26). The disc design has many advantages over the ball type valve. The obvious size reduction not only reduces weight and volume but provides faster response with the concommitant reduction in pressure gradient and regurgitation. The excursion is about 50% that of the ball type valve thus eliminating any interference with the ventricle sacs during systole - a definite advantage (Figure 4.27). The valves performed faultlessly and as previously mentioned have been incorporated into the particular pump used in all tests to evaluate its performance. This type of valve is ideal for use in an artificial heart of the ventricle sac type.

4.5 Endurance Test

Endurance testing was carried out after all other tests. Both sides were set to pump in series at 72 beats per minute with 10 mm.Hg.

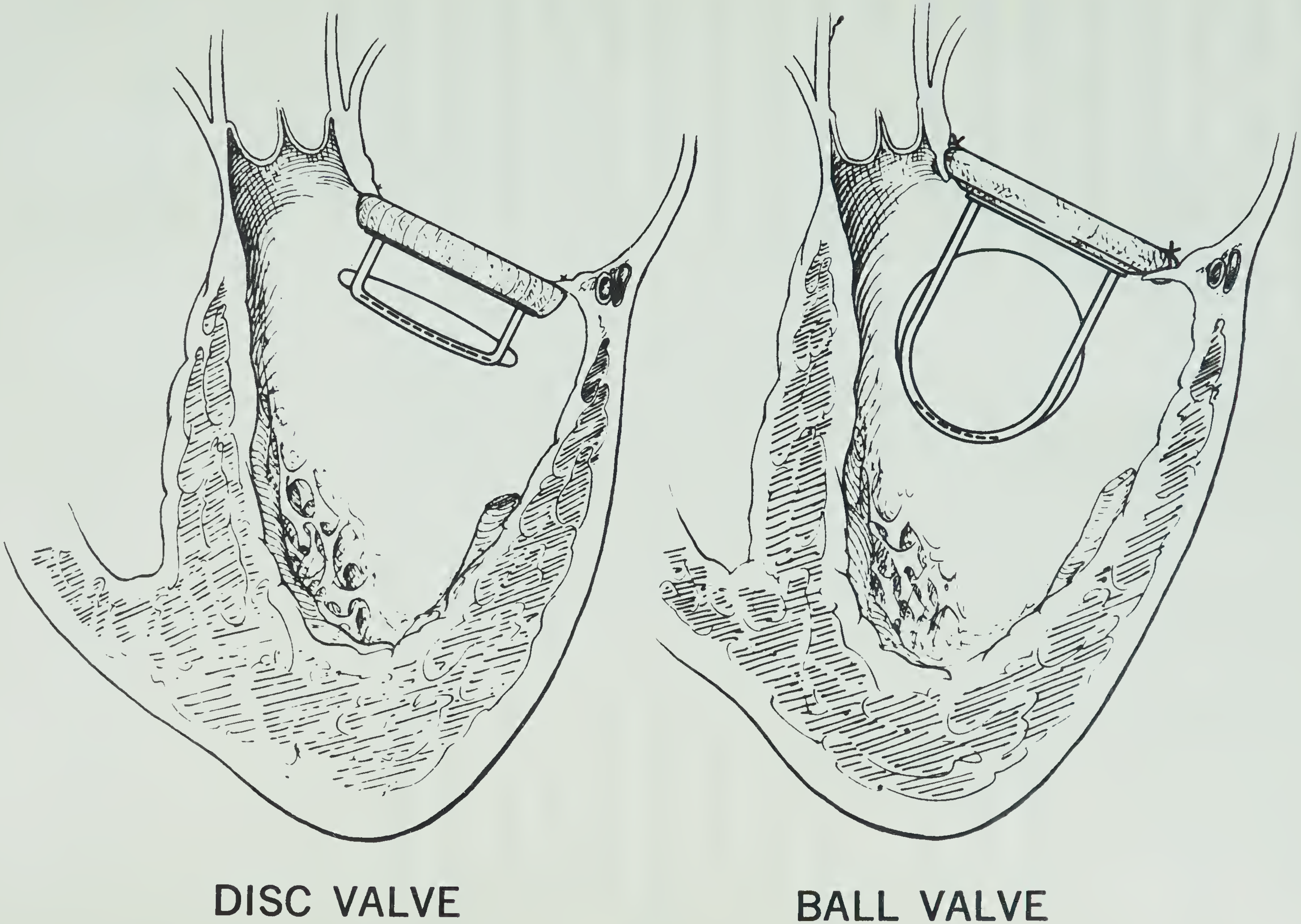

DISC VALVE
BALL VALVE

FIG. 4.27 VENTRICULAR EXCURSION OF DISC AND BALL TYPE VALVES

atrial pressure, 120/80 mm.Hg. aortic pressure, 55/30 mm.Hg. pulmonary pressure, and driving pressures of 3.6 and 2.3 psi respectively, to achieve an average output of six liters per minute. After five days of continued pumping both ventricles were maintaining an output of six liters per minute but a hairline crack on the inner surface of the polyurethane casing of the left ventricle was beginning to propagate transversely across the upper flat side. The crack had occurred several weeks earlier during a test for maximum output at a driving pressure of about 10 psi. By the seventh day the crack was fully across the ventricle and separating during systole. The crack did not affect output due to its peculiar location where the sac is always fixed to the casing. By the ninth day the crack had reached the curved side of the ventricle thus causing an air leak and output dropped to two liters per minute. At this time the left pump was stopped and the right side continued to pump faultlessly until stopped the following (tenth) day. Upon examination, the right side was found to be undamaged and suffered no loss in output during the ten days pumping. The failure of the left ventricle could be rectified in future by a lamination of glass fibre material in the polyurethane.

CHAPTER V

CONCLUSIONS AND SUGGESTIONS FOR FURTHER WORK

5.1 Conclusions

A pneumatically driven total replacement artificial heart has been developed which interacts with the inlet and outlet pressures and flow rate while maintaining good physiological pressures and cardiac output. The pumps are capable of producing flow rates satisfying human requirements up to and including moderate work at any pressures demanded by the body. The pump is similar to the natural heart in weight and size and its cyclic action is at normal heart rates providing output pressure wave forms with contours comparable with those produced by the natural heart.

The testing apparatus is limited to artificial circulations and cannot be used to evaluate degradation of blood and other body parts affected by the pumping characteristics of the artificial heart. The pump has been shown to provide acceptable blood flow and pressure but its effect on the body would have to be evaluated under in vivo conditions. The pump design is acceptable for experimental implantation in animals for short term tests.

5.2 Suggestions for Further Work

The first stage of continued research would be that of more extensive in vitro testing of the pump design. This would include continued improvement of materials and fabrication techniques, evaluation of different prosthetic valves, evaluation of the driving and timing

mechanism according to Starling's law, and evaluation of fatigue of component parts of the pump in the simulated circulation unit.

The second stage would involve several animal experiments to form a basic test and evaluation of the pump under real clinical conditions. This stage would include the standardization of venous and arterial connections, the development of a suitable transplantation technique, and the choice of pressure and flow monitoring techniques, extracorporeal circulation, and general instrumentation. During this stage, the pump design would undergo continual modifications to facilitate such things as ease of surgery, removal of trapped air, and orientation of pressure lines. The pump would not require a scaling in size since in vivo studies would be conducted with human sized animals; more specifically; either sheep and/or calves. Only the geometry of the blood vessel attachments would require adjustment according to the animal in which the pump were to be implanted. At the end of this stage, survival pumping times should be long enough to justify the following development.

The third stage would include an examination of single parameter changes upon survival time. These would include: evaluation of allografted or zenografted valves versus prosthetic valves; incorporation of bonded heparin or dacron vellour on blood handling surfaces as antithrombogenic agents; hemolytic and thrombogenic effects, and frequency effects. Since the basic design relies on Starling's regulation, the validity of this choice would be investigated in depth and the overall performance of the pump and control mechanism would be closely examined in a systematic manner.

Following the third stage of development the potential of the pump's clinical use in humans would be examined. As previously mentioned such decisions would be greatly influenced by the success or failure of cardiac allografting techniques. The first clinical application would likely be that of temporary support of a patient awaiting a suitable allograft.

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APPENDIX A

CALCULATION OF BODY SURFACE AREA

Body surface area is calculated from the following formula developed by Dubois in 1936[4] for use in metabolism studies:

$$\text{Body surface area} = (0.007184)(W^{0.425})(H^{0.725})$$

where body surface area is in square meters

W is weight in kilograms

H is height in centimeters

The formula is accurate to within less than 2%[4] and Stead in 1950[4] calculated the body surface area of the average man to be 1.73 square meters. N.A.S.A. suggests an average body surface area of 2 square meters for calculations made from Figure 2.2. For example, a person 5 ft.-8 in. tall weighing 195 lbs. would have a surface area of 2 square meters.

APPENDIX B

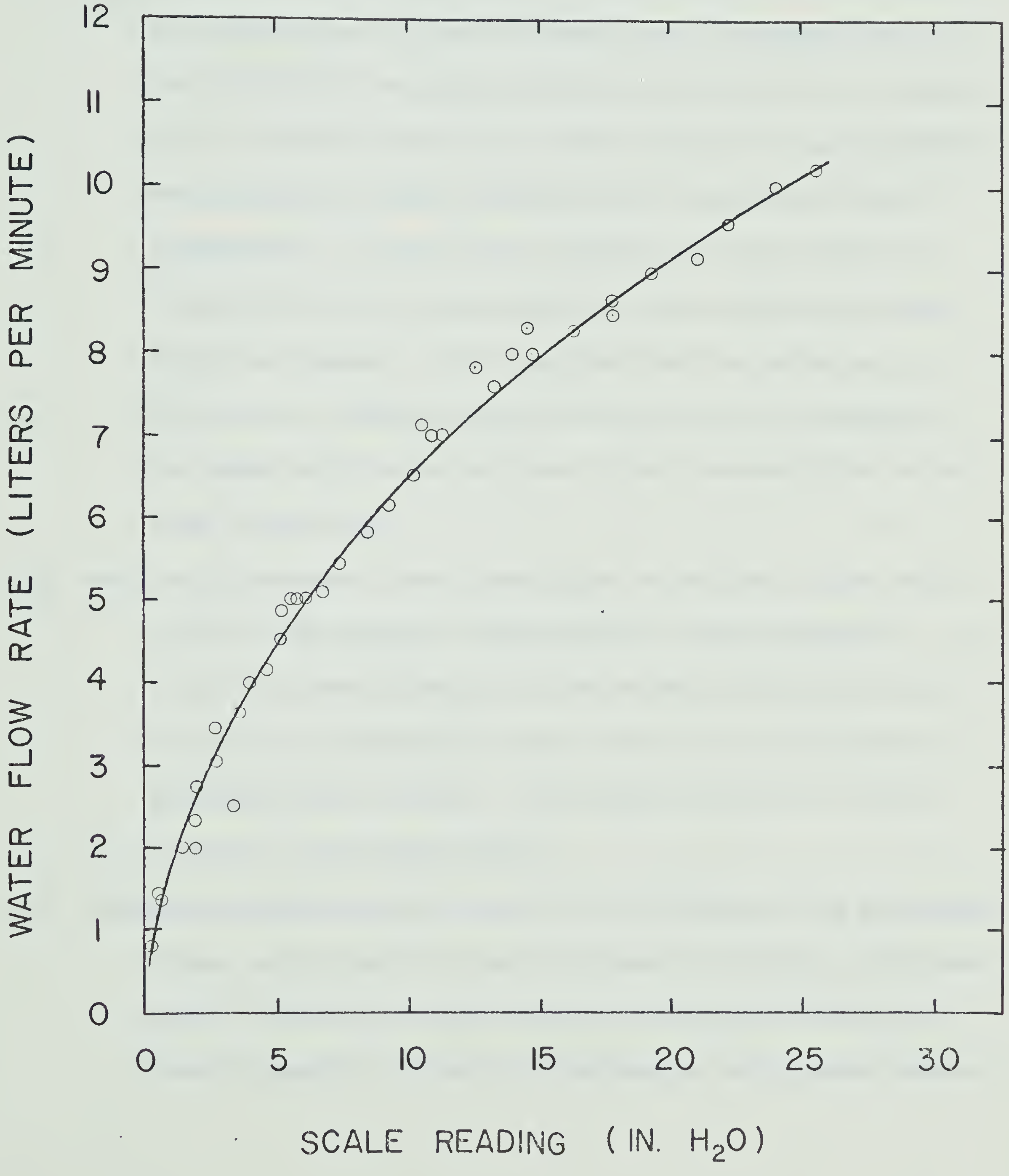

FIG.B.1 ORIFICE METER CALIBRATION CURVE

APPENDIX C

NOTES ON MATERIALS

C.1 Many materials were incorporated for the forming of the prototype sac forms before the use of dental wax. Both modelling clay and plasticine are easy to shape but do not polish or smooth well. The pink dental wax is ideal since it is very workable when softened by gentle heating but is very hard at room temperature. It can also be smoothed to a high degree by flame polishing the surface with a torch, melting away small cracks and gouges. It is important that the prototype be very smooth; otherwise discontinuities will be impressed in the rubber molds which may cause stress concentration in the final dipped sacs.

C.2 Dow-Corning produces a room temperature vulcanizing rubber which is ideal for mold making, requiring very little equipment. It is a catalytic free-flowing silicone rubber which cures in 24 hours at room temperature into a hard tear-resistant mold of excellent heat stability. The product is sold as Silastic "D" R.T.V. mold making rubber.

C.3 Although the dental wax was excellent for forming of the prototype it was not suitable for casting since it exhibited a high degree of contraction upon cooling. White paraffin wax was found to exhibit little or no contraction and produced excel-

lent castings of good smooth surface finish. The product is available as Esso Parawax.

C.4 Two types of air drying liquid latex were used in the dipping of sacs. Type A required four dippings to acquire a thickness of about 55 mills. Sacs of two or three dippings did not provide the strength required to constrain high aortic pressure, developing large balloon-like bubbles in the aorta and bursting. 50 mills is thick enough to withstand any physiological pressure and is thin enough not to be too resilient which would affect atrial expansion and collapse possibly producing vacuum effects in the ventricle during diastole. Type A dried in a few hours to a pale brown rubber with smooth surfaces. Type B latex dried much quicker with a mottled outer surface requiring seven to eight dippings to acquire a thickness of 50 mills. Type B dries to a more eye-pleasing, cleaner-looking pale yellow, but due to its rough outer surface texture was abandoned for continued use of Type A. Type A liquid latex is produced by Continental Rubber of Canada Limited and Type B by General Latex and Chemicals Canada Ltd. as Vultex Flexible Mold Facing.

C.5 Several early pumps were constructed with less than 8 to 10 coats of polyurethane and consequently fractured at driving pressures from 6 to 10 psi. Fractures always occurred on the flat side of the ventricle, cracking transversely just below the valves. 8 to 10 coats, or a thickness of about 50 to 60 mills withstood

up to 12 to 15 psi before fracturing. The material sets with a large content of small bubbles. These bubbles have no apparent effect on the strength of the polyurethane but could perhaps be eliminated by adoption of a dipping technique for application. The material is a specially-prepared two component plastic produced by Endura Manufacturing Company, Edmonton, and is labelled 1N-2C-A and 1N-2C-B.

C.6 The air inlet/outlet port is a length of Tygon tubing, 3/8 inch i.d. Early pumps were made with the port tubing at right angles to the ventricle casing. This was not satisfactory since the sac sometimes blocked off the vent before complete diastole causing only partial filling of the ventricle. The problem was solved by attaching the vent to the ventricle at a much smaller angle allowing the port to be slot shaped and about 5 cm. in length eliminating any possibility of port blockage.

APPENDIX D

MEASUREMENT OF ATRIAL PRESSURE

Atrial pressure in this and all other tests refers to the pressure measured at the center of the inflow tubes connecting to the atria. The pumps were connected to the test chambers horizontally rendering the measured inlet pressure as an average of the inlet pressure (Figure D.1). The point at atrial pressure measurement is critical since a change of one mm.Hg. can be responsible for a change in flow rate of 3 or 4 liters per minute. The curves given (Figure 4.2) are plotted against mean atrial pressure which may vary considerably depending upon what is decided to be mean atrial pressure (Appendix E). Since the heart is located in the thoracic cavity the effective filling pressure of the heart is determined not only by intra-atrial pressure but also by intra-pleural pressure. That is, it is determined by the transmural pressure which is equal to intra-atrial pressure minus intra-pleural pressure. Therefore inhalation and exhalation has an effect upon the cardiac output curve. It does not alter the level of the plateau but only shifts the curve horizontally (Figure D.2). By altering the point of atrial pressure measurement in the pump its output function curve could also be shifted to almost anywhere between the curves of Figure B.2. It is for this reason that average atrial pressure has been measured, keeping in mind that the shape of the function curve and its maximum are of most importance. The most desirable position of the curve

[illegible]

[illegible]

[illegible]

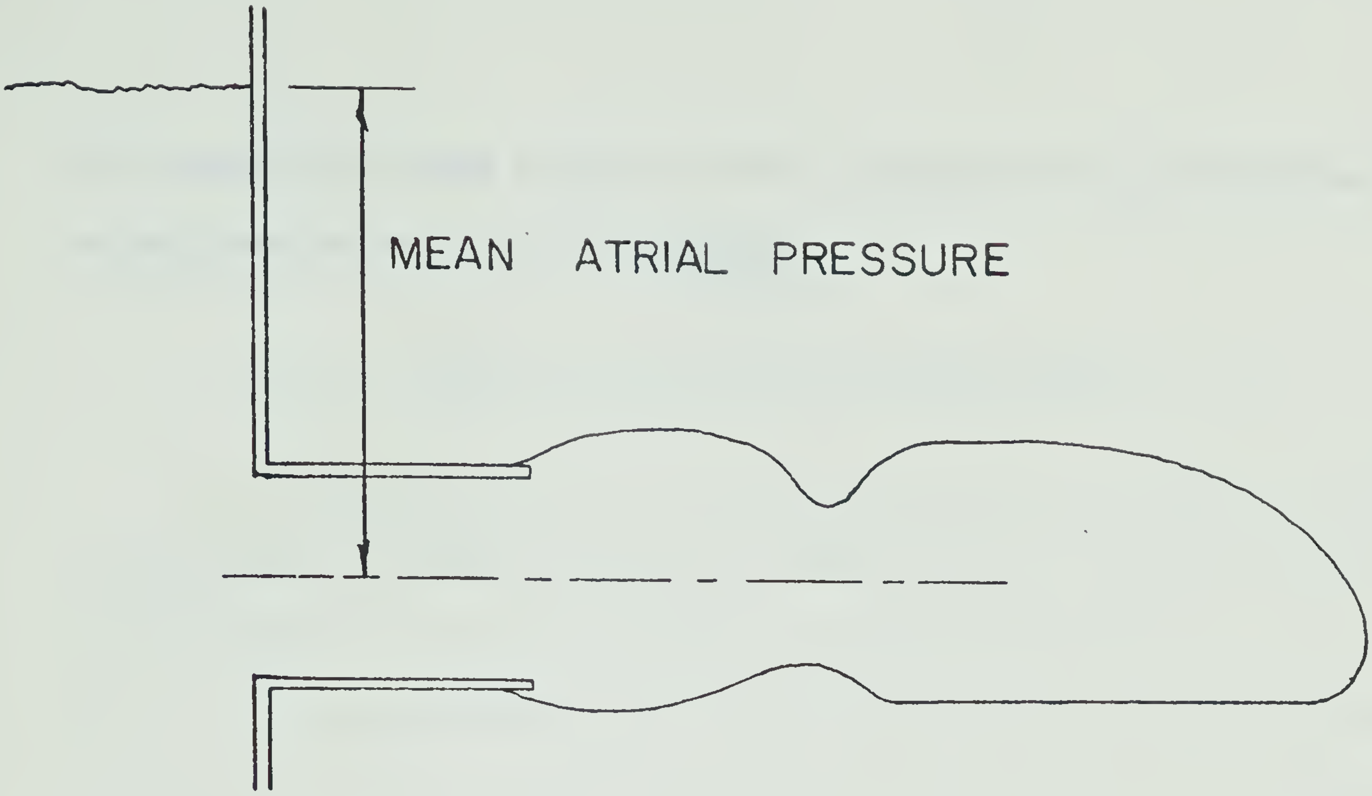
MEAN ATRIAL PRESSURE

FIG. D.1 MEASUREMENT OF ATRIAL PRESSURE

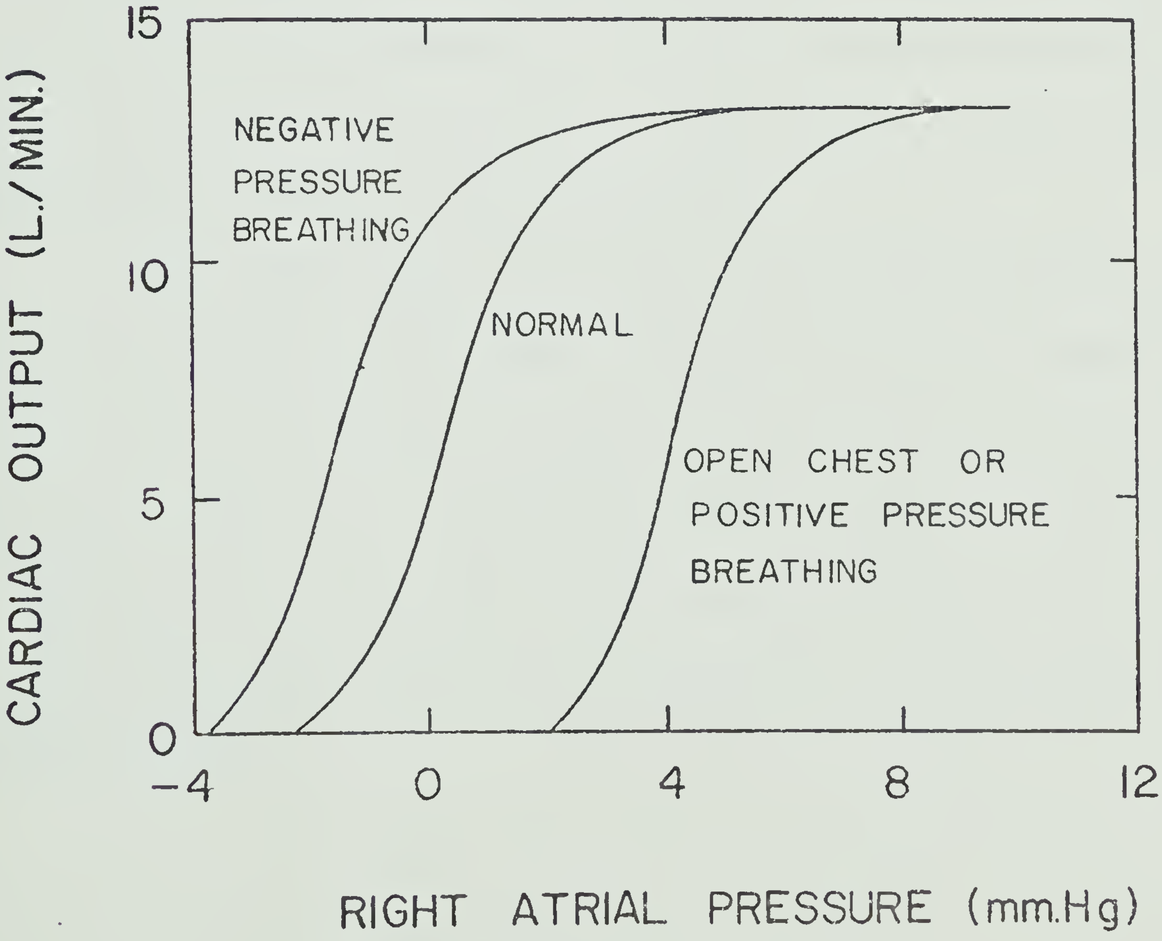

FIG. D.2 STARLING'S REGULATION -- BREATHING

for a particular pump along the atrial pressure axis could only be established under in vivo conditions.

APPENDIX E

SENSITIVITY OF CARDIAC OUTPUT CURVE

The sensitivities of cardiac output curves (Figure 2.3) referred to are extracted from Guyton (1963)[18] and according to him the precise curves have been calculated in the following way:

The relative shapes of the two curves have been determined from curves of this type measured in both open-chest and closed-chest dogs based principally on data published by Sarnoff (1955) and additional data recorded in his own laboratories (Crowell 1962, and Stone 1963). Then the curves have been extrapolated to the human being by means of the following basic assumptions. The normal outputs of both ventricles are 5 liters per minute, the normal right atrial pressure is 0 mm.Hg., the normal left atrial pressure is 4 mm.Hg. and both unstimulated ventricles can increase their outputs almost three-fold when their respective atrial pressures rise high enough.

These normal curves change their slopes when subjected to different physiological conditions. Sympathetic and para-sympathetic stimulation alone can change the sensitivity of the right ventricular output curve from 0.4 to 8 liters per minute per mm.Hg. Since the heart will function over a very large range of sensitivities, in vivo tests would be necessary to establish the importance of sensitivity of output to atrial pressure.

APPENDIX F

EXTRAPOLATION OF EXPERIMENTAL ANIMAL DATA TO HUMAN DATA

Most publishings of cardiac function curves and pressure traces are those recorded in experimental animals. Through comparison with limited data on output curves and pressure traces from human beings the contours appear to be almost identical. For this reason most published data for humans is extrapolated from data taken from experimental animals.

APPENDIX G

PRESSURE RECORDINGS

Pressure recordings from within the pump were difficult to read owing to the vibrations being picked up by the transducer; particularly noticeable at low pressures. These vibrations are believed to be caused partly by fluctuating driving pressure and partly by vibrations set up within the pump itself initiated by valves opening and closing and by rapid expansion and contraction of the chambers.

A great deal of the fluctuation in driving pressure was caused by the Tygon tubing connecting the pump to the air supply valves. An experiment was performed to examine this effect. A transducer was fitted to the end of the tubing that is normally connected to the pump and the driving unit was set in operation at a pressure of 10 mm.Hg. The subsequent recording (Figure G.1) displays clearly the build up of pressure as the tubing expands during systole and the subcritically damped harmonic motion at the beginning of diastole with sub atmospheric pressures. By removing the tubing and connecting the transducer directly to the outlet port of the valve the recording (Figure G.2) displays a far more rapid build up of pressure and no subcritically damped harmonic motion at the beginning of diastole. Clearly, the tube alone is a cause of vibration recorded within the pump since any fluctuation in driving pressure will be reflected within the chambers of the pump.

The in vitro test set-up provided no damping facility to iso-

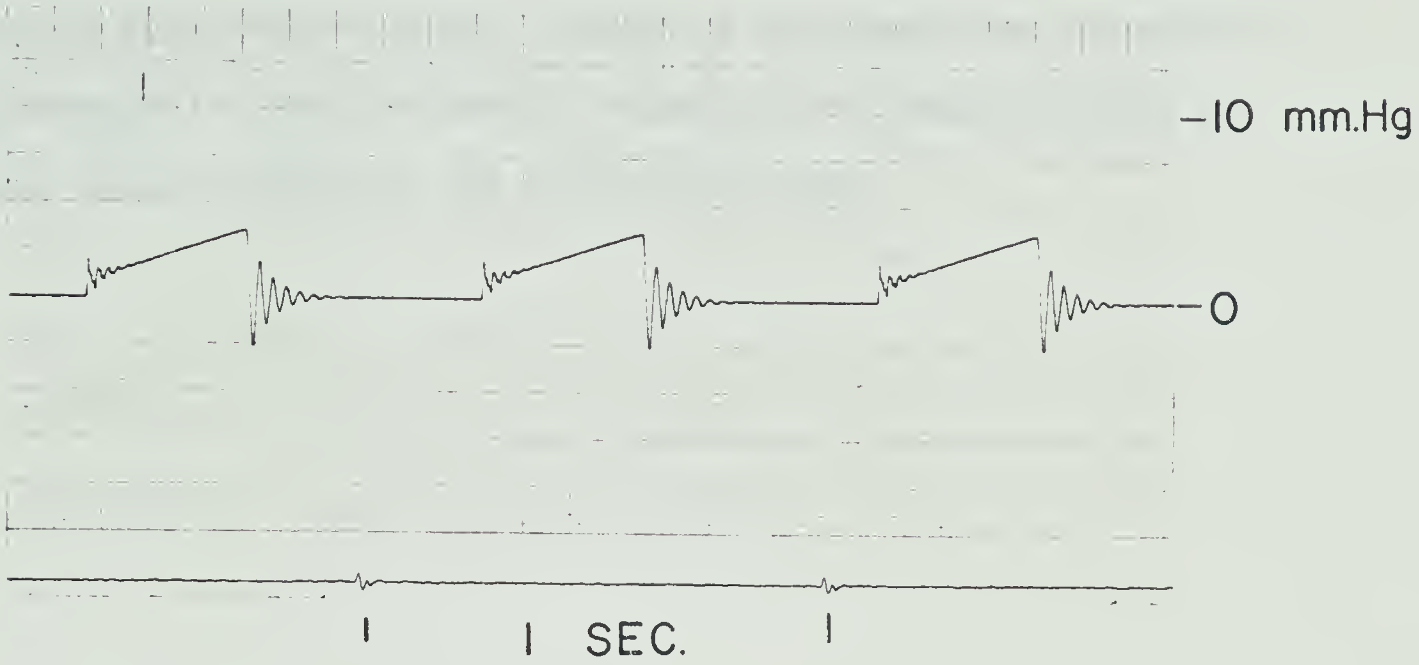

FIG. G.1 PRESSURE RECORDING - WITH TUBING

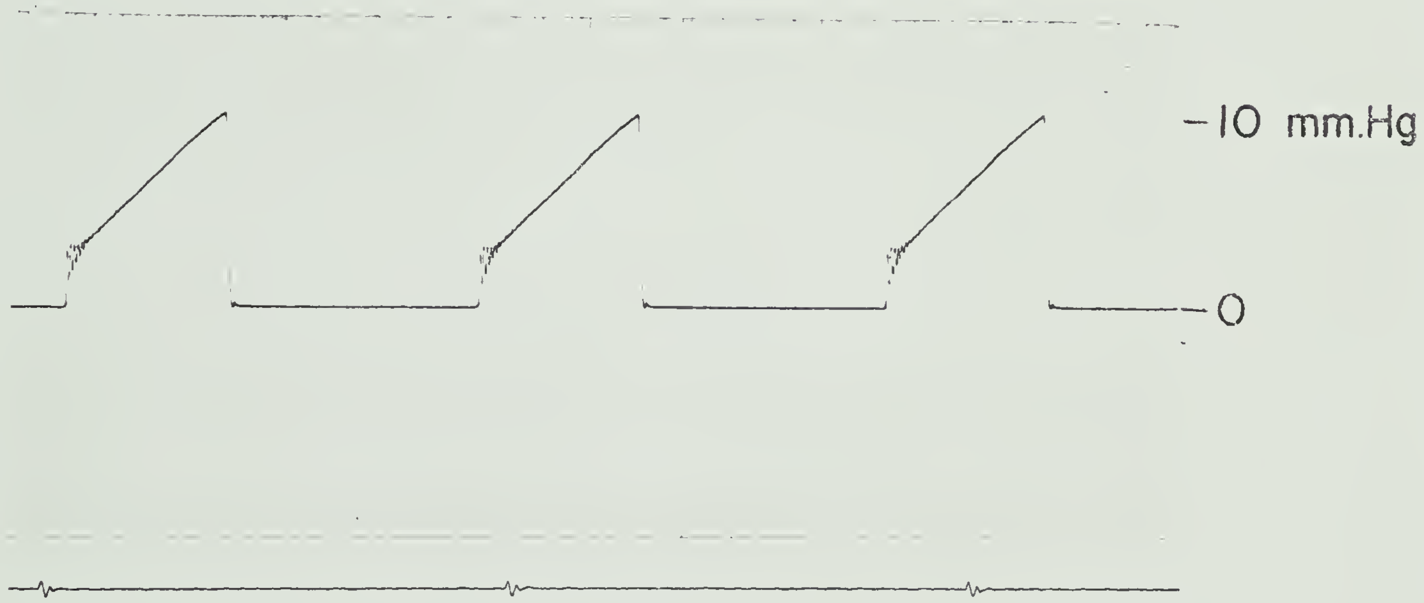

FIG. G.2 PRESSURE RECORDING - WITHOUT TUBING

late the pump from vibrations. Under in vivo conditions vibrations in the pump would likely be greatly reduced by the damping effects of blood vessel connections and surrounding organs.

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